

EPAUnited States Environmental Protection Agency
Washington, DC 20460**Work Assignment**

Work Assignment Number

2-03

☐ Other☐ Amendment Number:

Contract Number

EP-C-11-005

Contract Period 01/01/2011 To 12/31/2013

Base

Option Period Number 2

Title of Work Assignment/SF Site Name

Incorporation of New Technolog

Contractor

ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW

3.1, 3.3, 3.4, 3.6

Purpose:



Work Assignment



Work Assignment Close-Out



Work Assignment Amendment



Incremental Funding



Work Plan Approval

Period of Performance

From 01/01/2013 To 12/31/2013

Comments:



Superfund

Accounting and Appropriations Data



Non-Superfund

Note: To report additional accounting and appropriations data use EPA Form 1900-89A.

SFO
(Max 2)

2

3

1

2

3

4

5

DCN
(Max 6)Budget/FY
(Max 4)Appropriation
Code (Max 6)Budget Org/Code
(Max 7)Program Element
(Max 9)Object Class
(Max 4)

Amount (Dollars)

(Cents)

Site/Project
(Max 8)Cost Org/Code
(Max 7)

Authorized Work Assignment Ceiling

Contract Period:

Cost/Fee:

LOE:

01/01/2011 To 12/31/2013

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated:

Cost/Fee:

LOE:

Cumulative Approved:

Cost/Fee:

LOE:

Work Assignment Manager Name Shamima Akhter

(Signature)

(Date)

Branch/Mail Code:

Phone Number 202-566-0000

FAX Number:

Project Officer Name Shirley Harrison

(Signature)

(Date)

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

Other Agency Official Name Shirley Harrison

(Signature)

(Date)

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

Contracting Official Name Sandra Stargardt-Licis

(Signature)

(Date)

Branch/Mail Code:

Phone Number: 513-487-2006

FAX Number:

**PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-11-005
WORK ASSIGNMENT # 2-03**

Title: Incorporation of New Technologies to Support Criteria Development and Implementation

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Alternate WAM: John Ravenscroft
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E-mail: ravenscroft.john@epa.gov

Period of Performance: January 1, 2013 through December 31, 2013

Contractor SOW: 3.1, 3.3, 3.4, 3.6

Background:

An important goal of the Clean Water Act is to protect and restore waters for swimming. A key component in the CWA framework for protecting and restoring waters for swimming is State adoption of water Quality Standards (WQS) to protect swimmers from illnesses associated with "microbes" in the water. One of the EPA's key roles is to recommend recreational water quality criteria (under section 304(a) of the CWA) for adoption by the States. These EPA recommended criteria have been historically based on fecal matter in the water; in the 1960's the Federal Government recommended certain levels of fecal coliform as the recreational criteria and in 1986 EPA recommended certain enterococci and E. coli as its new recreational criteria.

In order to continue to provide increased protection to swimmers and for development of Total Maximum Daily Loads (TMDLs), National Pollutant Discharge Elimination System (NPDES) permitting requirements and water quality listings, EPA is now poised to revise its ambient water quality criteria. The old criteria developed in 1986 was mainly based on enumerations of Fecal Indicator Bacteria (FIB) using culture-based methods, some of which were originally developed over a century ago. The advent of scientific methods particularly in the molecular measurements of diverse microbial populations, analytical chemistry, virology, genomics including metagenomics warrant reevaluations of the 1986 criteria development process. Research advances have revealed many of the shortcomings and uncertainties associated with the 1986

water quality criteria. EPA is committed to develop new recreational water quality criteria for all water body types by 2012. Before new criteria can be developed, it is imperative that EPA undertakes critical research, analyze existing research data so that a scientifically defensible and health protective criteria can be adopted.

New molecular assays with intrinsic characteristics of high sensitivity, specificity, and reproducibility allow more direct enumeration of potential pathogens in recreational water. For example, Immunomagnetic Separation / Adenosine Triphosphate (IMS/ATP), TaqMan Protein Assays, fluorescent-based microbe detection assays allow enumerations of indicator organisms very reliably. EPA is contemplating inclusion of Quantitative Polymerase Chain reaction (qPCR) based enumerations of FIBs that can rapidly produce actionable results as opposed to the 24-48 hours that is now needed for culture based laboratory analysis. However, before new technologies can be incorporated in criteria development, numerous regulatory hurdles and related research needs must be met.

EPA anticipates a need to find out how we can use the data from the new technologies in the criteria development in the absence of epidemiological studies.

Quality Assurance:

The tasks in this Performance Work Statement (PWS) require the use of secondary data/analyses and fall under the scope of the approved contract-level QAPP. Consistent with the Agency's quality assurance (QA) requirements, the contractor must assure the quality and analyses of the secondary data and other data collected to be used under this work assignment.

The Contractor shall discuss with the EPA WAM if any of the specific work assignment tasks are not readily covered under the approved QAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a work assignment-specific QAPP supplement, which must be approved by the EPA WAM before activities covered by the additional QA language begin under this work assignment.

PERFORMANCE WORK STATEMENT (PWS):

Task 1: Work plan and monthly progress reports

The contractor shall develop a detail work plan and cost estimate for each task outlined in this work assignment. The plan should contain, but not limited to, work-flowchart, elaborate schedule (task-wise), staffing plan and qualifications of proposed staff, budget for each task and level of effort (LOE). Prior to the submission of the work plan, the contractor shall consult with the EPA WAM via conference call to mitigate any potential issues that need clarifications. The contractor shall include information on plans to manage work and control contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency. The plan should be submitted no later than fifteen (15) working days after receiving this work assignment.

This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs' broken out by the tasks in this work assignment.

Task 1.2: Information Quality Guidelines

The Contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines and shall complete the Checklist for Influential Information as needed for each deliverable from this work assignment as they may be used in Agency decision-making and/or will be publicly available documents. The EPA WAM will provide the checklist to the Contractor. The Contractor shall provide a memorandum describing how the planned product(s) developed meet EPA's Information Quality Guidelines checklist. As part of that memo, the Contractor shall document the quality assurance procedures it used in developing the deliverables under this PWS. The Contractor shall provide the memo at the time it delivers the Final Summary Report. The Contractor shall have a teleconference with the EPA WAM to discuss the Guidelines and the Contractor's role in completing the checklist.

Task 2: Develop methodology for incorporation of new methods without epidemiological studies

In order to develop new robust Recreational Water Quality Criteria (RWQC), EPA is considering major technical methodologies that will allow future linkage to RWQC in the absence of additional epidemiological studies. EPA understands that the foremost requirements for RWQC include: RWQC should depend on the indicators that can be quantified reliably, robustly, and reproducibly; RWQC should protect individuals exposed to recreational waters; RWQC should protect children as they are more exposed and susceptible to pathogens; and RWQC should be scientifically defensible for application in a wide variety of geographical locations.

This PWS builds on previous work that is described in a report from a previous work assignment (WA 2-14, Task 2), under contract EP-C-07-036 titled *Options to Incorporate New Technologies and Methods into Recreational Water Quality Criteria without Additional Epidemiological Studies* (referred to as Report 2-14 hereafter).

The contractor shall further develop the water quality approach presented in Report 2-14. The below descriptions are from Report 2-14.

Water Quality Based Approach - Indicators that are Directly Related to "Standard" Indicators that are in Turn Related to Epidemiology Data

If RWQC are based on a particular indicator-method combination (referred to here as the "standard" indicator), an alternative indicator-method combination may be related to the health effects association via linkage of the alternative indicator to the standard indicator. For example, epidemiological studies have established an association between *Enterococcus* density as determined by qPCR and the incidence of GI illness. This health effects curve may be used to establish a qPCR *Enterococcus* water quality criterion that is protective of health at a chosen

level of risk. The question "what *Enterococcus* density via membrane filtration provides the same health protection as the qPCR criterion?" may be answered as follows. A model relating culturable *Enterococcus* density to qPCR-measured *Enterococcus* can be established, and uncertainty in the model and conditions for which the model is valid may be defined. The model can then be used to determine the *Enterococcus* culture density equivalent to the *Enterococcus* qPCR RWQC. This process is illustrated in Exhibit 2 below.

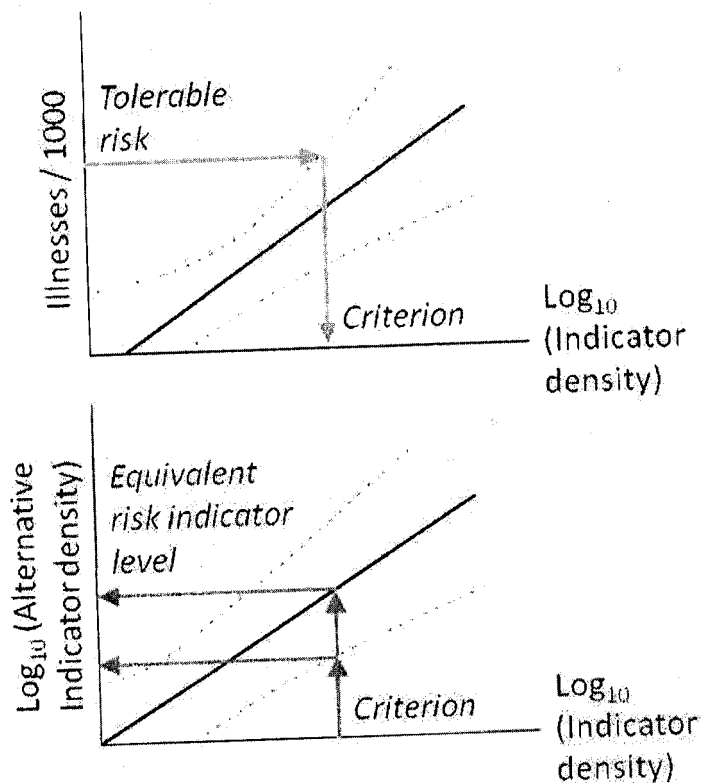


Exhibit 2. Linking to Health Effects Data via Equivalence of Water Quality Data

For this method to be viable, a robust, verifiable relationship must be established between the standard and alternative indicator(s). Establishing this relationship requires: (1) selection of a "gold standard" method against which alternative methods are compared; (2) rigorous demonstration of a relationship between the standard and alternative indicator entailing demonstration that results of assays of environmental samples of the two indicators are consistently related (e.g., when one rises, the other also rises), recoveries of the methods are within an acceptable range, and uncertainty and variability of the alternative method is not significantly greater than that of the gold standard; and (3) establishment of the conditions/settings for which the relationship between the standard and alternative indicator is valid.

EPA is interested in methods that may be incorporated for water quality assessment in the future as well as those that may be adopted in the near term, including those that can possibly be incorporated into water quality standards in the absence of epidemiological studies.

Report findings

The contractor shall submit a draft report of findings, including any recommendations for addressing potential "problem areas" in the analysis and potential use of the results in RWQC implementation. The contractor shall incorporate any additional analyses into revisions of the draft report upon receipt of additional datasets from EPA WAM.

EPA is interested in focusing on the performance of these methods to show that a common risk level can be applied resulting in a similar health protection standard for all Clean Water Act (CWA) purposes. The two approaches should be developed such that there is clear statistical support for how the approaches can be used to link new methods/technology to 2012 RWQC implementation without undertaking any additional epidemiological studies.

It is of paramount importance that incorporation of the new methods/technology should result in equivalent health protection. EPA is interested in methods that may be incorporated for water quality assessment in the future as well as those that may be adopted in the near term, including those that can possibly be incorporated into water quality standards in the absence of epidemiological studies.

The report will include discussion of the strength of the statistical support for both approaches and possible limitations with the approaches.

Travel: Local travel is anticipated for this Task. No travel outside of the Washington, D.C. metro area is required.

Task 4: Develop Technical Support Documents

In order to develop Technical Support Documents for criteria implementation, EPA is anticipating detailed analyses of the Task 2 that shall be the basis of completing Task 4. This work shall provide a tool for states to develop new methods or indicators for their water quality standards on a site-specific basis. Information on demonstrating the relationship between two-indicator method combinations shall be characterized under this task. The contractor shall be aware of the following time-line to generate the deliverable. The deliverable will go for internal/management review followed by the external peer review. Afterwards, the peer reviewed deliverable will again be evaluated by internal/management team.

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|--|--------------------------|
| Draft deliverable and Charge to Internal Reviewer (ORD/HECD) | February 15, 2013 |
| • Response/Incorporation – | February 15 - 22, 2013 |
| • Management review - | March 1 – March 15, 2013 |
| • Conduct peer review | April 15, 2013 |
| • Final Peer Review Report - | May 30, 2013 |
| • Response to peer review comments – | June 1 - 30, 2013 |
| And incorporation of any changes to the deliverable (ICF) | |

After Peer Review

- Internal Review HECD - July 1 – 15, 2013
- Management review - August 1 - 21, 2013
- Final deliverable - September 2013

Period of Performance/Milestones: It is the Contractor's responsibility to coordinate with EPA WAM while conducting these tasks.

| Task | Milestone | Date due |
|------|--|--|
| 1 | Work Plan | Within fifteen (15) calendar days of receipt of WA |
| 1 | 1.1 QAPP | Within 3 weeks of receipt of WA |
| 1 | Kick-off meeting with EPA WAM | 1 week after WP approval |
| 2 | Compare method performance | 3 weeks after WP approval |
| 2 | Submit draft report of initial findings | 6 weeks after WP approval |
| 2 | Incorporate additional studies into analyses, if identified (Task 2) | Incorporate any additional analyses into revisions to draft report upon receipt from EPA |
| 4 | Draft Report | 2 months after WP approval |
| 2&4 | Revised Report | TBD |

Knowledge and Skills Required: Contractor shall have expertise in preparing the aforementioned materials and be knowledgeable with the various fields of discipline discussed in this work assignment. The Contractor shall have practical experience in statistical methods and have analysis and have advanced credentials in environmental microbiology. The contractor shall be familiar with the use of fecal indicator organisms, microbiological analytical methods (including molecular techniques) water monitoring, applications of epidemiological data, determination of human exposure to environmental contaminant sources, and gastrointestinal disease endpoints, and other factors associated with needs in recreational water quality and CWA 304(a) criteria development.

General Requirements of the Work Assignment and Schedule:

Due Dates: The Contractor shall provide due dates that are mutually acceptable with the EPA WAM. The Contractor shall notify the EPA WAM in advance, if a due date will not be met and request a revised date.

Delays: The Contractor shall make every effort to ensure there are no Contractor-caused delays. If a delay is inevitable, it is the Contractor's responsibility to notify the EPA WAM at the first sign of said delay. A revised schedule will then be worked out.

Draft Documents: The Contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. EPA WAM will provide comments on draft submissions prior to submission of final documents.

Final Documents: The Contractor shall submit final documents both electronically and in hardcopy to EPA WAM.

Final Documents: The Contractor shall revise and incorporate all EPA's comments and submit final documents both electronically and in hardcopy (Microsoft version 2003 or higher) to EPA WAM. The Agency may decide to publish the report on the web. If this occurs, the report will need to be 508 compliant and the COR will provide appropriate technical direction.

Final Peer Reviewed Document: Upon receipt of the EPA's external expert peer-review of the Contractor's Final Written Report, the EPA WAM will provide the Contractor with the recommended edits and modifications. The Contractor shall address all recommended peer-review modifications. Changes will be documented in a separate report for the record to describe how the peer-review comments were incorporated into the final report. The Contractor shall provide the revised final report (and documented changes to the report) to the EPA WAM for review. Upon the EPA WAM's approval, the Contractor shall send the final revised peer-reviewed report in Microsoft Word, version 2003 or higher, to the EPA WAM.

MEETINGS, CONFERENCES, TRAINING EVENTS, AWARD CEREMONIES AND RECEPTIONS:

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA PO as needed and provided to the Contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the EPA PO.

**PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-11-005
WORK ASSIGNMENT # 2-03 Amendment 1**

Title: Incorporation of New Technologies to Support Criteria Development and Implementation

Work Assignment Manager: Shamima Akhter
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Period of Performance: January 1, 2013 through December 31, 2013

Contractor SOW: 3.1, 3.3, 3.4, 3.6

Purpose of Amendment:

The purpose of this amendment is to provide additional LOE to support Task 4, *Develop Technical Support Materials*. The deliverables under this task have necessitated additional rounds of reviews and editing by the EPA WAM and EPA Management that were not anticipated when the original work assignment was prepared. The additional resources will continue to support Task 4 and the preparation of the Technical Support Materials for external peer review and their related activities. In addition, to addressing EPA internal management review comments.

The quality assurance and monthly progress reports, still apply to this amendment. The contractor shall provide a cost estimate in response to this amendment.

Deliverables for task 4:

TSM to peer review (3 more drafts)
Response to comment draft 1
Response to comment draft 2
Post peer review draft 1
Post peer review draft 2

Post peer review draft 3
TSM galley proofs (up to 2)
TSM 508 PDF

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|---|----------------|---|-------------------------------|----------------------------|----------------------------|-------------------------------|------------------|---------|-------------------------|--------------------------|
| EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment | | Work Assignment Number 2-04 | | | | | | | | |
| | | <input type="checkbox"/> Other <input type="checkbox"/> Amendment Number: | | | | | | | | |
| Contract Number EP-C-11-005 | | Contract Period 01/01/2011 To 12/31/2013 Base Option Period Number 2 | | | | | | | | |
| Contractor ICF INCORPORATED, L.L.C. | | Title of Work Assignment/SF Site Name QMRA Activities to Support | | | | | | | | |
| Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval | | Period of Performance From 01/01/2013 To 12/31/2013 | | | | | | | | |
| Comments: | | | | | | | | | | |
| <div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund <div style="text-align: center;">Accounting and Appropriations Data</div> <input checked="" type="checkbox"/> Non-Superfund </div> | | | | | | | | | | |
| SFO (Max 2) <input type="checkbox"/> Note: To report additional accounting and appropriations data use EPA Form 1900-69A. | | | | | | | | | | |
| Line | DCN (Max 6) | Budget/FY (Max 4) | Appropriation Code (Max 6) | Budget Org/Code (Max 7) | Program Element (Max 9) | Object Class (Max 4) | Amount (Dollars) | (Cents) | Site/Project (Max 8) | Cost Org/Code (Max 7) |
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| Contract Period: | | Cost/Fee: | | LOE: | | | | | | |
| 01/01/2011 To 12/31/2013 | | | | | | | | | | |
| This Action: | | | | | | | | | | |
| Total: | | | | | | | | | | |
| Work Plan / Cost Estimate Approvals | | | | | | | | | | |
| Contractor WP Dated: | | Cost/Fee: | | LOE: | | | | | | |
| | | | | | | | | | | |
| Cumulative Approved: | | Cost/Fee: | | LOE: | | | | | | |
| | | | | | | | | | | |
| Work Assignment Manager Name John Ravenscroft | | | | | | Branch/Mail Code: | | | | |
| _____ (Signature) | | | | | | _____ (Date) | | | | |
| Project Officer Name Shirley Harrison | | | | | | Phone Number 202-566-1101 | | | | |
| _____ (Signature) | | | | | | _____ (Date) | | | | |
| Other Agency Official Name Shirley Harrison | | | | | | Branch/Mail Code: | | | | |
| _____ (Signature) | | | | | | _____ (Date) | | | | |
| Contracting Official Name Sandra Stargardt-Licis | | | | | | Phone Number: 202-566-1107 | | | | |
| _____ (Signature) | | | | | | _____ (Date) | | | | |
| | | | | | | FAX Number: | | | | |
| | | | | | | Branch/Mail Code: | | | | |
| | | | | | | Phone Number: 513-487-2006 | | | | |
| | | | | | | FAX Number: | | | | |

**Performance Work Statement
ICF Contract # EP-C-11-005
Work Assignment #2-04**

Title: QMRA Activities to Support Criteria Development and Implementation

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Alternate WAM: Sharon Nappier (Mail Code 4304T)
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Period of Performance: January 1, 2013 through December 31, 2013

****Note:** No CBI data will be needed in the course of this work assignment.

Contractor PWS: 3.1, 3.3, 3.6

Background: EPA is issued new CWA 304(a) Recreational Ambient Water Quality Criteria (AWQC) in December 2012. The science underpinning the new criteria describes human health effects and water quality studies conducted in waters impacted primarily by human sources of fecal contamination. EPA would like to better understand the risks associated with other fecal sources and the potential wet weather impacts on surface waters. Quantitative Microbial Risk Assessment (QMRA) has been identified as a tool that the Agency can use to complement existing health data and to better understand the relative risks associated with non-human fecal sources of surface water contamination. The Agency's previously supported QMRA efforts have indicated that there are potentially significant differences in health risks associated with different sources of fecal contamination and additional efforts are needed to better inform the regulatory framework. This work assignment covers various aspects of further development and application of QMRA in support of Recreational AWQC development and implementation.

Quality Assurance: The tasks in this Performance Work Statement (PWS)) require the use of secondary data/analyses and fall under the scope of the approved contract-level QAPP. Consistent with the Agency's quality assurance (QA) requirements, the contractor must assure the quality and analyses of the secondary data and other data collected to be used under this PWS.

The Contractor shall discuss with the EPA WAM if any of the specific work assignment tasks are not readily covered under the approved QAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a WA-specific QAPP supplement, which must be approved by the EPA before activities covered by the additional QA language begin under this PWS.

Performance Work Statement: The scope in this PWS will fall under the following task areas:

Task 1: Work plan, monthly progress reports and quality assurance

Task 1.1: Work plan

The contractor shall develop a work plan to address all tasks in this work assignment. The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If a subcontractor(s) is proposed and subcontractors are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

This task also includes monthly progress and financial reports. The monthly progress report shall indicate in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs delineated by the tasks in this WA. These reports should also indicate an estimate for the next month by task and if any lagging costs are expected. EPA realizes these estimates are just approximate values and is interested in having this information for internal budgeting purposes.

Task 1.2: Information Quality Guidelines

The Contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines and shall complete the Checklist for Influential Information as needed for each deliverable from this work assignment as they may be used in Agency decision-making and/or will be publicly available documents. The EPA WAM will provide the checklist to the Contractor. The Contractor shall provide a memorandum describing how the planned product(s) developed meet EPA's Information Quality Guidelines checklist. As part of that memo, the Contractor shall document the quality assurance procedures it used in developing the deliverables under this Work Assignment. The Contractor shall provide the

memo at the time it delivers the Final Summary Report. As directed by the EPA WAM, the Contractor shall have a teleconference with the EPA WAM to discuss the Guidelines and the Contractor's role in completing the checklist.

Task 2: General Project Support and Development of Technical Support Guidance

EPA is planning to make available Quantitative Microbial Risk Assessment (QMRA) guidance to States for consideration in developing site-specific Water Quality Standards (WQS) packages. Task 2 comprises the different facets of the QMRA guidance project and includes project planning, communication strategies, and guidance document development.

Task 2.1: Project planning and management

The Contractor shall conduct project strategic planning in conjunction with the EPA WAM. The purpose of this subtask will be to develop a comprehensive plan that includes all related tasks and deliverables in the context of the Agency's Recreational Ambient Water Quality Criteria (RWQC) and implementation guidance. The planning shall include a discussion of how each task will aid EPA in meeting its goals in relation to QMRA and the technical support guidance for implementation.

This task may require contractor travel to HQ for an initial planning meeting and quarterly update meetings thereafter during the period of performance of this work assignment. All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA PO as needed and provided to the Contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the PO.

The Contractor shall provide personnel knowledgeable in QMRA and also project planning and management for this process. Expertise in Microsoft Project (v. 2007) is preferred. The initial meeting is crucial to the entire overall work assignment and therefore will need to occur soon after the work assignment is received by the Contractor. Additionally, weekly update meetings between the EPA WAM and the Contractor shall be scheduled.

Deliverables under this subtask will include updating (as needed) schedules listing all QMRA-related work with interim and final deliverable dates and quarterly project updates delineated. Given that the various QMRA tasks, both previously conducted by HECD and under the current effort, have been conducted incrementally, these pieces fit together to form a substantive body of work for the Agency.

As part of the effort under this subtask, the Contractor shall include a discussion on the Agency's QMRA goals and objectives and how each of the tasks supports them. It is hoped that this exercise will also help to identify any gaps that will need to be addressed prior to the publication of the implementation guidance. Project milestones provided in this work assignment may be impacted by the results of this project planning. Any differences identified

in these due dates will need to be identified and communicated via technical direction from the EPA WAM.

Task 2.2: Project communication support:

The contractor shall, based on technical direction given by the EPA WAM, provide support in preparing interim project updates and other materials for internal and external audiences. These may include but are not limited to short briefing documents and PowerPoint presentations. The Contractor may also be directed to participate in and/or conduct briefings and meetings. The Contractor may also be directed to prepare reports for communication outside the EPA based on deliverables generated by tasks under this work assignment. The Contractor shall coordinate with the EPA WAM for the proper timing and need for these activities. A weekly update call with the EPA WAM will be required for this task, as needed.

A second major area under this task is Quantitative Microbial Risk Assessment (QMRA) outreach support. The Contractor shall assist EPA WAM with internal and external outreach to EPA management, both at Headquarters and with Regional offices, States, and other Stakeholder groups.

EPA needs to communicate its efforts to a broad audience. From engaging other scientists on technical issues to discussing regulatory actions with stakeholders and the public, EPA needs to be keenly aware of effective communication strategies. For all tasks under this work assignment, the Contractor shall discuss with the EPA WAM ways to achieve effective communication objectives. The audience for specific deliverables may be different even though the analytical approach may be similar. Questions to cover with the EPA WAM should address the audience and purpose of the deliverable, ideas for finding effective presentation strategies, suggestions for achieving the communication objectives given differing formats (e.g., written versus oral).

The Contractor may be requested to attend meetings of a scientific nature to present the results of the QMRA analyses to technical and non-technical audiences. All appropriate clearances and approvals required by Agency policy in support of any and all meetings shall be obtained by the EPA PO as needed and provided to the Contracting Officer. Work under meeting-related activities and expenses shall not occur until this approval is obtained and provided by the PO. Known at the time of submission of this work assignment is the following:

Conference – 2013 RWQC: A Vision for the Future
Water Resources Research Center, University of Hawaii

The information on the 2013 meeting was just announced as of the preparation of this work assignment. The Contractor shall engage with the EPA WAM to prepare poster presentations (for a mixed technical and regulatory audience) of appropriate QMRA topics from the other tasks completed in the previous contract year. The deadline for submission of abstracts is January 11, 2013.

Task 2.3: Development of QMRA Technical Support Guidance, QMRA framework:

The purpose of this task is to continue development and to produce communication materials for the use of QMRA in the development of site-specific recreational water criteria intended as the basis for water quality standards (WQS). Past efforts by the Contractor have concentrated mainly on non-human sources, but the framework itself should be robust enough to consider other differences or site-specific characteristics.

The Contractor shall continue development of the Quantitative Microbial Risk Assessment (QMRA) framework for the purposes outlined above. This task shall build upon previous efforts conducted under B-04, Task 2.2 (QMRA guidance: how to conduct a QMRA for ambient waters, data needs and analytical approaches) and 1-04, Task 2.3. The goal for this task will be to develop and to communicate the process by which QMRA can be used to derive alternative site-specific ambient water quality criteria for recreational use waters that will, in turn, be used to assemble a water quality standards (WQS) package. This deliverable can be considered part of the overall technical support guidance as detailed in other tasks below, and shall include a description and discussion of the process and framework whereby QMRA could be used as a basis for a site-specific WQS package.

The deliverable shall address the way(s) a State can determine if any given site is a good candidate for the development of a site-specific water quality standards package based on a QMRA-derived criteria value. The Contractor shall include a discussion of the components of water quality standards package and how QMRA can assist in developing a site-specific water quality criteria value. To complete this part of the deliverable, the Contractor shall meet with the EPA WAM, WQS coordinators or other personnel in SHPD and the Regions. Logistics of these meetings may require the Contractor to attend meetings at EPA HQ. The Contractor shall address the differing approaches a State could use in running a QMRA (i.e., differing level of effort related to complexity of analysis).

The Contractor shall also consider the implications that the WQS package will be evaluated by EPA regional and headquarters personnel who will not necessarily have a technical background in microbiology, public health or risk assessment methodologies. Therefore, it will be **critical** that the Contractor consider the end-user audience as the deliverable is being developed. Technical material shall be transparently and sufficiently conveyed. The narrative shall be thoroughly developed and any graphical materials shall be explained completely. No assumption should be made that the audience will internalize figures or tables. These considerations are quite important as this material will be used to inform the policy decisions needed for QMRA to be used effectively. Much consideration should be given to the current paradigm in this area; end-users that are not familiar with risk assessment in general and hampered by misunderstandings related to the past and current technical bases for the nationally recommended recreational water quality criteria. It will be crucial that the Contractor develop effective communication and outreach materials if QMRA is to be applied effectively.

Task 2.4: Development of QMRA Technical Support Guidance, Volume A:

The purpose of this task is to develop a guide for use by States and localities for the purposes of deriving via the QMRA framework discussed in Task 2.3, site-specific criteria, notably for waters predominated by non-human sources of fecal contamination, for inclusion into WQS. This volume will need to be published by the Agency by the end of October 2013, so the Contractor will need to plan accordingly. This timeframe also includes substantial time for management and 3rd party peer review.

This guide should also provide information to EPA Regions who are tasked to evaluate State WQS packages. Volume A of this guidance shall concentrate on how to determine if a water body is eligible for the development of site-specific criteria, what information can be used to provide a line of evidence approach for determining sources of fecal contamination (i.e., how to build a sanitary characterization), differing approaches to conducting a Quantitative Microbial Risk Assessment (QMRA) (i.e., incorporate information from Task 2.3), the information needs for conducting a QMRA (at each level of effort), how to conduct a QMRA (i.e., how to build a transparent, clear, concise and reasonable risk assessment in support of public policy), deriving a site-specific water quality criterion, preparing a site-specific water quality standards package, and other topics as needed to be specified by the EPA WAM (and in consultation with HECD's partners in SHPD). The main goal for this deliverable is produce guidance for States to use in developing microbial Water Quality Standards (WQS) that are scientifically defensible, protective of the recreational designated use, and meet EPA standards for consideration and potential approval.

This task will require the Contractor to attend meetings with the EPA WAM and other staff at EPA Headquarters during the period of performance for the purposes of project updates, planning and communication. The Contractor shall anticipate travel to DC once per quarter for a total of 4 meetings at EPA HQ.

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA PO as needed and provided to the Contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the PO.

Task 2.5: Development of QMRA Technical Support Guidance (TSG), Volume B:

The deliverable under this task shall provide the end user a sufficiently detailed background on QMRA and the use of microbial risk assessment in developing site specific water quality standards. This volume shall provide the technical bases for the material in Volume A (Task 2.4). While this volume is purposefully technical in nature, it should still be produced in a manner that would be accessible to the end user. This volume is also scheduled to be published by the end of October 2013.

The Contractor shall include the following topics in the scope of technical materials: assessing human health risks from fecal contamination in surface waters; use and application of epidemiology in development of water quality standards around the world; use of risk assessment to help interpret and extend observational studies; factors affecting occurrence, prevalence, fate and transport of pathogens and fecal indicator bacteria in surface waters; potential effects of management practices on sources of fecal contamination and implications to potential human health risks; and, other topics as specified by the EPA WAM.

Task 2.6: Development of QMRA Technical Support Guidance (TSG), Volume C:

The purpose of this task is to document a series of QMRAs conducted on recreational use waters. Each QMRA would be made available or peer reviewed/published separately. This volume will discuss each and give more information to explain how each risk assessment fits into context with the materials in volumes A and B. The context that will need to be developed will consist of a compare and contrast discussion with EPA recommended ambient water quality criteria for recreational waters and other risk assessments. The Quantitative Microbial Risk Assessments (QMRAs) can be discussed as 'case studies'. This compilation volume will be peer reviewed with Vol B and should be considered to be on the same schedule for completion.

At present, the EPA WAM envisions this "volume" to comprise a report and will reference the risk assessments discussed and where to find them (should copyrights allow, those assessments can be included as appendices). Existing material for inclusion in this volume includes: Ohio case study; Boqueron case study, Chicago Area Waterways (CAWS) case study, and Southern California Coastal Water Research Project (SCCWRP) case study. However, the SCCWRP case study may occur on a parallel track and not be complete in time for a full discussion in Volume C. The Contractor shall coordinate with the EPA WAM early and often to better scope out other potential material for this volume.

The Contractor may be required to attend meetings with SCCWRP to discuss planning, scoping, conduct, or analyses associated with the case study project. As mentioned before, all appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA PO as needed and provided to the Contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the PO.

Task 2.7: Support for Southern California Coastal Water Research Project (SCCWRP) case study

The LA Regional Water Control Board, SCCWRP and EPA are collaborating on a project to characterize human health risks via QMRA from recreational water exposure at a predominantly non-human fecal-impacted beach in southern California. The potential beach locations are in Southern California. The second main goal of this effort is to use the QMRA results to inform the development of a site-specific water quality standard for submission and evaluation by EPA Region 9. The third goal of this effort is to document the experience as a "case study" for potential application at other candidate sites.

Results from this effort will be used to compile three primary reports that will form the basis for achieving the three project goals. First, a technical results report will be written by the project group to estimate the potential human health risks from recreational exposure at the study beach and to inform the derivation of a site-specific water quality objective based on an equivalent benchmark level of public health protection as discussed in EPA's recommended recreational water quality criteria. Second, a 'policy' report would discuss how to develop a site-specific alternative water quality standard, from a process viewpoint, based on the results contained in the technical report and would cover federal, state, and local considerations. Finally, a non-technical communications package would be developed for use in engaging stakeholders, higher level management, and the public. This package would provide a layman's version of the study purpose, design, and results through plain language outreach materials.

The Health and Ecological Criteria Division's participation in this project will be to aid in the planning and scoping of the project, provide QMRA support, and engage the regional water control board, EPA Region 9, and the local NGOs in the development and evaluation of a site-specific water quality standard package. The Contractor shall assist the EPA WAM with the QMRA-related aspects of this project. The Contractor shall participate in discussions with the EPA WAM along with SCCWRP and the workgroup to help with project planning, scoping, QMRA analysis, interpretation of the results, and development of communication strategies for the purpose of deriving site-specific recreational water criteria for a beach predominantly impacted by non-human fecal contamination. QMRA-related efforts under this task should help to inform activities under Task 2.6. The Contractor shall discuss the practical experiences learned from this project to help improve, refine, or change the current approach detailed in the TSM.

Workgroup meetings are anticipated to occur approximately twice per year in the greater Los Angeles, CA area. The Contractor may be required to attend these meetings to supply QMRA-related expertise and guidance to the workgroup on the scientific and technical aspects of the project. All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA PO as needed and provided to the Contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the PO.

Task 2.9: Updating the Microbial Risk Assessment Tools Document

OST previously prepared a microbial risk assessment (MRA) document specifically for water media. This document has been through internal editing and peer review by the EPA's Science Advisory Board. The Contractor has updated and submitted the draft document to EPA as requested in the last contract year. The draft is currently under EPA review. The Contractor shall incorporate EPA WAMs comments based on this review and prepare the document for final approval and publication.

The revised document should need a final internal QA check by the Contractor prior to submission to the EPA WAM. The Contractor shall also develop a briefing package for the

document to be used in communicating with internal EPA management in the document approval process. The briefing package should include a brief synopsis of the document and potential questions and answers geared toward non-risk assessors.

Task 3: QMRA anchoring

Task 3.1: Marine National Epidemiological and Environmental Assessment of Recreational Water (NEEAR) studies

A revised report was submitted by the Contractor on 11/26/12. The Contractor shall update the report to reflect EPA comments. The results of this effort will be included in the TSG Volume B. The Contractor shall discuss with the EPA WAM the benefit of having the results peer reviewed by a scientific journal or as part of Volume B (and peer reviewed separately). Once updated (as discussed below), the Contractor shall also submit as part of the revised draft a project summary aimed at a non-technical audience. The summary should provide the important conclusions to be drawn from the analysis along with a discussion of how these results fit into context with the existing knowledgebase (not necessarily restricted to the area of QMRA).

The Contractor was in the process of updating the analysis of the QMRA anchoring report for the Surfside epidemiology study with the available sanitary characterization information as this work assignment was being prepared. The source of fecal contamination affecting the Surfside study area was determined to be non-human. Based on the observed source(s), as documented in OST's sanitary survey report, this Quantitative Microbial Risk Assessment (QMRA) should mirror previous efforts where non-human agricultural fecal sources were characterized.

Task 3.2: Marion et al. study

A revised report was submitted in a memorandum by the Contractor in December 2012. This report is currently being reviewed by EPA at the time of the preparation of this work assignment. Upon receiving comments from the EPA WAM, the Contractor shall forward the revised report to the Ohio State University collaborators for their review. After that is complete, an updated report suitable for internal management review shall be submitted to EPA WAM within two weeks of receiving OSU input. Comments from this review shall be discussed with the EPA WAM and the report revised accordingly. A final report suitable for peer review shall be submitted to EPA WAM by the end of March 2013.

This collaboration provides an excellent opportunity for the EPA to engage with external researchers. The Contractor shall assist in maintaining the good relationship EPA has established with the OSU staff. Any ideas for improving this collaboration will be quite welcome to the EPA WAM. Additionally, the contractor may be requested to provide facilitation assistance with the OSU group in order to maintain sufficient progress towards peer reviewing the QMRA deliverable.

Task 3.3: Boqueron

The Contractor submitted a draft report on 11/06/12. This version is currently under EPA management review. Any comments from this review shall be discussed with the EPA WAM and the report revised accordingly. A final report suitable for peer review shall be submitted to the EPA WAM when these revisions are complete.

Task 3.4: QMRA anchoring communication support

The Contractor shall develop communication materials for each of the task 3 QMRA reports aimed at non-technical, policy-oriented audiences. Materials aimed at the general population may also be needed and shall be prepared by the contractor when technical direction is received. The Contractor shall discuss the importance of the findings of the Task 3 efforts, how they fit into context with other QMRA and other results, and any science or policy implications. Other topics to be included in these materials will be discussed as needed with the Contractor.

Additionally, the Contractor may be required to attend one meeting at EPA Headquarters to present results to management and staff. Timing for the meeting has not been finalized at the time of the submission of this work assignment; however, ODCs for one visit to EPA Headquarters are included.

Task 4: Relative QMRA refinement

Task 4.1: Evaluating source and receptor locations

This task shall continue support for efforts begun under B-04. The contractor shall meet with the EPA WAM to develop a list of modeling needs (e.g., FRAMES-related) to support implementation of QMRA. The contractor shall also coordinate with the EPA WAM to discuss with other EPA personnel about advancements in dose response modeling (e.g., animal studies translated to human health estimates).

The contractor shall continue to discuss with the EPA WAM and ORD-Athens personnel the current capabilities for fate and transport modeling in the context using the QMRA framework for deriving water quality standards. HECD will need to have these discussions documented for use with communication with management. This task is considered to require a low level of effort during the period of performance.

Task 4.2: Relative QMRA refinement: QMRA analysis of mixed fecal sources

The Contractor submitted a report for EPA management review in the last contract year. This report is still under review at this time.

The Contractor shall update the report incorporating EPA WAM's comments. Comments from this review shall be discussed with the EPA WAM and the report revised accordingly. A final report suitable for peer review shall be submitted to the EPA WAM when these revisions are complete.

Task 5: Primary and Secondary Contact evaluations

The purpose of this task is to evaluate health risks associated with different water-based activities performed in the US. This task will be part of the scientific basis for policy measures to place activities into appropriately protective recreational use categories (e.g. primary contact recreation, secondary contact recreation), and to determine the level of water quality necessary to protect individuals engaging in each of these activities.

The Contractor submitted a draft Quantitative Microbial Risk Assessment (QMRA) report during the base year under this task. For this work assignment, the Contractor may be asked to provide responses to questions from EPA WAM on the analysis and conclusions contained in the deliverable. The Contractor should consider this task 'low level of effort' for purposes of developing the workplan.

Task 6: Children's Health, Sensitive Subpopulations, Alternate Study designs, and Environmental Justice evaluations

Task 6.2: Alternate epidemiology study designs

EPA is interested in comparing results from epidemiology studies conducted with alternative study designs. The Agency has conducted past efforts in this area to identify appropriate data sets and design an analytical approach for that data. The Contractor shall build upon those past efforts and secure data from an RCT (randomized control trial) epidemiology study sufficient for a comparative analysis with a PC (prospective cohort) design. The Contractor shall conduct the following activities:

Coordinate with the investigators on an RCT study to obtain the raw data from that study and re-analyze the results using the statistical methods employed by Wade and colleagues for the EPA epidemiology studies. This analysis will provide an indication of whether or not results from RCTs and PCs can be compared directly and will help to answer the question of whether the differences observed in existing epidemiology studies are due to the study design or other factors.

Use a QMRA framework to translate results from an RCT to one that is comparable to a PC study. Conduct sensitivity analyses to identify the model parameters that most strongly influence the results. Compare the results with those from the first analysis. The contractor shall report findings to EPA WAM in a memorandum, including potential next steps for this analysis.

Efforts conducted in the base year resulted in the identification of potential datasets for this analysis. However, there has been reluctance from external researchers to share the data needed for this comparison. This subtask is included here to maintain the potential for this analysis in this option year, but the Contractor should consider this subtask as a placeholder and low priority. Should data become available, the Contractor shall discuss the path forward with the EPA WAM before any LOE is expended on this task.

Task 7: Chicago Area Waterways (CAWS) QMRA

The goal of this task is to develop a QMRA-based evaluation of human health risks from exposure to the Chicago Area Waterways. This evaluation should consider the range of exposures covered by the traditional metrics of primary and secondary contact recreation.

The Contractor submitted a draft QMRA using both literature-reported values for pathogens in secondary treated, but non-disinfected effluent and the results from pathogen monitoring on the CAWS. The report is currently under review and comments will be sent to ICF from the EPA WAM. These comments will need to be addressed in the next version of the report.

There is considerable interest within EPA, both at HQ and in Region 5, in this particular QMRA. While this is not a final expectation, the Contractor may be requested to visit Region 5 in order to discuss other potential analyses. This visit is not definite, but ODCs have been included in case the need for the meeting materializes.

The Contractor shall revise the draft as a risk assessment based on EPA WAM's comments. The Contractor shall submit a final version of the report to the EPA WAM within two weeks of receiving EPA comments.

The Contractor shall submit technical and non-technical briefing materials along with the revised assessment. These materials may be a "two-pager" and/or a slide presentation and will be discussed during the weekly meeting.

Milestone/Deliverable Table

| Task | Task # | Milestones and Due Dates |
|--|---------------|---|
| Task 1: Work plan, monthly progress reports and quality assurance | | |
| Workplan | 1.1 | Within 15 calendar days of receipt of work assignment |
| Information Quality Guidelines | 1.2 | Discuss with EAP WAM within 15 calendar days of receipt of work assignment. IQG checklists due with final deliverable (can be included with QA materials). |
| Task 2: General Project Support | | |
| Project Planning and Management | 2.1 | Initial planning meeting to be held within 15 calendar days of receipt of work assignment. Meeting shall update project Gantt chart, goals and objectives statement, and gap analysis due within 2 weeks of initial meeting. Drafts of this deliverable would be expected at the close of the initial meeting. Subsequent meetings to be held roughly every quarter thereafter. |
| Project Communications Support | 2.2 | After the workplan approval, throughout the period of performance. See meeting dates in WA text. Other communication materials will be dependent on the analytical results. Revisions to the P4 paper due within 2 weeks of receiving comments from OW and ORD. |
| QMRA TSG: QMRA Framework | 2.3 | Include as part of Volume A.. |
| QMRA TSG: Vol A | 2.4 | Draft for mgmt review: By 2/16/13; Draft for peer review, 4/15/13; Final by 9/15/13 |
| QMRA TSG: Vol B | 2.5 | Same schedule as Vol A. |

QMRA TSG: Vol C

2.6

Vol C mainly consists of reports prepared individually under other tasks - refer to those tasks for component schedules. For supplemental text expanding on those reports: same schedule as Vol A.

Support for SCCWRP study

2.7

Provide QMRA related planning, scoping, analysis, interpretation, and site-specific standard derivation support. Attend workgroup meetings at SCCWRP approximately once per year. Ongoing low level of effort throughout the period of performance.

Task 3: QMRA Anchoring

Marine NEEAR reverse QMRA

3.1

Updated report within 1 month of receiving EPA comments. Discuss incorporation of results into TSG Vol B and venue for peer review and publication at weekly WA meeting at weekly meeting.

Marion anchoring QMRA

3.2

Update report based on EPA and OSU comments and other analyses, with 2 weeks of receiving OSU input. Updated draft will be reviewed by HECD management. Mgmt comments will be addressed and final report to be submitted for peer review by end of March, 2013.

Boqueron QMRA

3.3

Updated draft within 1 month of receiving EPA comments. Updated draft will be reviewed by HECD mgmt. Mgmt comments will be addressed and final report to be submitted for peer review by end of February, 2013.

| | | |
|--|-----|---|
| QMRA Communications Support | 3.4 | Non-technical, policy oriented communication materials, within 1 month of workplan approval. Materials for general audiences due date to be determined by technical direction. Meeting and presentation at EPA HQ to be determined. |
| Task 4: Relative QMRA refinement | | |
| Evaluating sources and receptor locations | 4.1 | Ongoing throughout the period of performance. Periodic teleconference calls (e.g., bimonthly) with HECD, ICF, and ORD-Athens. Deliverables for this task include notes of teleconference meetings and synopses of modeling developments and capabilities used for internal communication. |
| Refinement of QMRA analyses of mixed fecal sources | 4.2 | Updated report within 2 weeks of receiving EPA comments. Mgmt comments will be addressed and final report to be submitted for peer review. |
| Task 5: Primary and Secondary Contact | | |
| Communications support | | Low LOE effort; as needed throughout the period of performance. |
| Task 6: Sensitive Subpopulations and alternate study designs | | |
| Alternative epidemiology study design | 6.2 | Low LOE effort; continue efforts to identify RCT data sets. |
| Task 7: CAWS QMRA support | | |
| Update draft QMRA addressing EPA comments and inclusion of additional questions/information. | 7.1 | Updated report based on EPA comments due within 2 weeks of receiving comments from EPA HQ and Region 5. |

General Requirements of the Work Assignment and Schedule:

Due Dates: The Contractor shall provide due dates that are mutually acceptable with the EPA WAM. The Contractor shall notify the EPA WAM in advance, if a due date will not be met and request a revised date.

Delays: The Contractor shall make every effort to ensure there are no Contractor-caused delays. If a delay is inevitable, it is the Contractor's responsibility to notify the EPA WAM at the first sign of said delay. A revised schedule will then be worked out.

Draft Documents: The Contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. EPA WAM will provide comments on draft submissions prior to submission of final documents.

Final Documents: The Contractor shall submit final documents both electronically and in hardcopy to EPA WAM.

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|--|----------------|----------------------|--|--|----------------------------|--|--|-------------------------|--------------------------|
| EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment | | | | | | Work Assignment Number 2-04 | | | |
| | | | | | | <input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000001 | | | |
| Contract Number EP-C-11-005 | | | Contract Period 01/01/2011 To 12/31/2013 Base Option Period Number 2 | | | Title of Work Assignment/SF Site Name QMRA Activities to Support Cri | | | |
| Contractor ICF INCORPORATED, L.L.C. | | | | Specify Section and paragraph of Contract SOW 3.1, 3.3, 3.6 | | | | | |
| Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval | | | | | | Period of Performance From 01/01/2013 To 12/31/2013 | | | |
| Comments: | | | | | | | | | |
| <div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund <div style="flex-grow: 1; text-align: center;">Accounting and Appropriations Data</div> <input checked="" type="checkbox"/> Non-Superfund </div> | | | | | | | | | |
| SFO (Max 2) <input type="checkbox"/> Note: To report additional accounting and appropriations data use EPA Form 1900-69A. | | | | | | | | | |
| Line | DCN (Max 6) | Budget/FY (Max 4) | Appropriation Code (Max 6) | Budget Org/Code (Max 7) | Program Element (Max 9) | Object Class (Max 4) | Amount (Dollars) (Cents) | Site/Project (Max 8) | Cost Org/Code (Max 7) |
| 1 | | | | | | | | | |
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| Authorized Work Assignment Ceiling | | | | | | | | | |
| Contract Period: | | Cost/Fee: | | | LOE: | | | | |
| 01/01/2011 To 12/31/2013 | | | | | | | | | |
| This Action: | | | | | | | | | |
| Total: | | | | | | | | | |
| Work Plan / Cost Estimate Approvals | | | | | | | | | |
| Contractor WP Dated: | | | | | Cost/Fee: | | LOE: | | |
| Cumulative Approved: | | | | | Cost/Fee: | | LOE: | | |
| Work Assignment Manager Name John Ravenscroft <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div> | | | | | | | Branch/Mail Code: Phone Number 202-566-1101 FAX Number: | | |
| Project Officer Name Shirley Harrison <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div> | | | | | | | Branch/Mail Code: Phone Number: 202-566-1107 FAX Number: | | |
| Other Agency Official Name Shirley Harrison <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div> | | | | | | | Branch/Mail Code: Phone Number: 202-566-1107 FAX Number: | | |
| Contracting Official Name Sandra Stargardt-Licis <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div> | | | | | | | Branch/Mail Code: Phone Number: 513-487-2006 FAX Number: | | |

Performance Work Statement
ICF Contract # EP-C-11-005
Work Assignment #2-04 Amendment 1

Title: QMRA Activities to Support Criteria Development and Implementation

Work Assignment Manager: John Ravenscroft (Mail Code 4304T)
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Period of Performance: Work Assignment Amendment through December 31, 2013

Purpose of Amendment: The purpose of this amendment is to provide additional funding for Tasks 2, 3, 4 and 7. Deliverables under these tasks in the original approved workplan have necessitated additional rounds of development, review and editing by the EPA WAM and EPA management that were not anticipated when the original work assignment was prepared. At a minimum, the Contractor shall work closely with the EPA WAM to develop drafts of the reports listed below that are written in a clear and concise manner for the intended audience. The drafts will then go through internal technical, policy and management review. There may be significant comments to address after each step. In addition, the Contractor shall include an estimate for preparing final reports for EPA publication, including 508 compliant PDF versions. The additional funding supplied by this amendment will help to prepare useful deliverables of sufficient quality for EPA. Additional funding is being provided for the deliverables under Tasks 2, 3, 4 and 7 include:

Task 2:

- 2.1 Weekly meetings with EPA WAM
- 2.2 New and revised briefing documents and presentation materials
- 2.2 P4 manuscript
- 2.2 Boquerón follow-up report
- 2.3 TSM Guide
- 2.4 QMRA TSM: Vol A
- 2.5 QMRA TSM: Vol B

2.6 QMRA TSM: Vol C
2.7 Communications materials
2.9 MRA Tools Document

Task 3:

3.1 Marine NEEAR QMRA report
3.1 Surfside QMRA report
3.2 Marion (Ohio) QMRA report
3.3 Boquerón QMRA
3.4 Related communications materials

Task 4:

4.1 Evaluation of source and receptor locations for QMRA
4.2 QMRA analysis of mixed fecal sources

Task 7: CAWS QMRA report

This amendment adds no new tasks or additional deliverables and existing specified tasks. The quality assurance and monthly progress reports, still apply to this amendment.

Because of the additional unanticipated review and re-writing steps for multiple deliverables under the original work assignment, it is anticipated that the additional funding supplied by this amendment may not be sufficient to fully fund all of the tasks. The Contractor shall provide as a part of the workplan submitted in response to this amendment a cost estimate for completion of all of the remaining tasks. The Contractor shall discuss with the EPA WAM a priority of completion for the remaining unfinished tasks in this work assignment. At the time of the preparation of this amendment, the preparation of the Technical Support Materials for external peer review, and their related activities, were the highest priority. This would include an internal management review step and responding to their comments prior to the peer review. Peer reviews will be conducted by a third party and not the Contractor.

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|--|----------------|----------------------|---|--|----------------------------|---|-----------------------------|-------------------------|--------------------------|
| EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment | | | | | | Work Assignment Number 2-07 | | | |
| | | | | | | <input type="checkbox"/> Other <input type="checkbox"/> Amendment Number: | | | |
| Contract Number EP-C-11-005 | | | Contract Period 01/01/2011 To 12/31/2013 Base Option Period Number 2 | | | Title of Work Assignment/SF Site Name Children's Risks from Fecal | | | |
| Contractor ICF INCORPORATED, L.L.C. | | | | Specify Section and paragraph of Contract SOW 3.1, 3.3, 3.6 | | | | | |
| Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval | | | | | | Period of Performance From 01/01/2013 To 12/31/2013 | | | |
| Comments: | | | | | | | | | |
| <div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund <div style="flex-grow: 1; text-align: center;">Accounting and Appropriations Data</div> <input checked="" type="checkbox"/> Non-Superfund </div> | | | | | | | | | |
| SFO (Max 2) <input type="checkbox"/> Note: To report additional accounting and appropriations data use EPA Form 1900-69A. | | | | | | | | | |
| Line | DCN (Max 6) | Budget/FY (Max 4) | Appropriation Code (Max 6) | Budget Org/Code (Max 7) | Program Element (Max 9) | Object Class (Max 4) | Amount (Dollars) (Cents) | Site/Project (Max 8) | Cost Org/Code (Max 7) |
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| Contract Period: 01/01/2011 To 12/31/2013 Cost/Fee: LOE: | | | | | | | | | |
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| Total: | | | | | | | | | |
| Work Plan / Cost Estimate Approvals | | | | | | | | | |
| Contractor W/P Dated: Cost/Fee: LOE: | | | | | | | | | |
| Cumulative Approved: Cost/Fee: LOE: | | | | | | | | | |
| Work Assignment Manager Name John Ravenscroft <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div> | | | | | | Branch/Mail Code: Phone Number 202-566-1101 FAX Number: | | | |
| Project Officer Name Shirley Harrison <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div> | | | | | | Branch/Mail Code: Phone Number: 202-566-1107 FAX Number: | | | |
| Other Agency Official Name <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div> | | | | | | Branch/Mail Code: Phone Number: FAX Number: | | | |
| Contracting Official Name Sandra Stargardt-Licis <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div> | | | | | | Branch/Mail Code: Phone Number: 513-487-2006 FAX Number: | | | |

**PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-11-005
WORK ASSIGNMENT #2-07**

Title: Children's risks from fecal contamination in recreational water

Work Assignment Manager: John Ravenscroft (Mail Code 4304T)
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Alternate WAM:
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Period of Performance: January 1, 2013 through December 31, 2013

Contractor SOW: 3.1, 3.3, 3.6

****Note:** No CBI data will be needed in the course of this work assignment.

Goal: The overall goal of this Performance Work Statement (PWS) is to examine multiple lines of evidence (Center for Disease Control (CDC) Recreational Water Illness outbreak data, risk assessment analyses and epidemiological data) to evaluate the potential that children have disproportionate risks of waterborne illness from recreational water contact.

Objectives:

1. Produce a comprehensive report for internal EPA evaluation detailing the known health information for children's waterborne illnesses from recreational water exposure. The report shall demonstrate an evaluation of the scientific literature, risk analysis (e.g., QMRA) and observational results (e.g., National Epidemiological and Environmental Assessment of Recreational Water (NEEAR) study reports).
2. Produce a draft and final report for external scientific peer review based on the information covered in objective 1.

3. Produce communications materials to accompany reports including: a 1 to 2 page nontechnical synopsis, a technical summary document written in non-academic style for a non-scientific audience, a 'questions and answers' (Q&As) document covering areas of potential inquiry from nontechnical and technical audiences (both internal and external), and others as determined by the EPA WAM via technical direction.

Methodology:

1. The Contractor shall combine previous efforts under WA B-07 and B-04 task 6.1 to compile a comprehensive evaluation of the potential health impacts on children from exposure to fecally-contaminated recreational water. This evaluation shall compare and contrast the potential health effects on the general population, as discussed in the current revisions of EPA's recreational water criteria for ambient waters.
2. The Contractor shall utilize the draft memos, including the data summary tables, prepared under B-07, including:
 - a. Children's health risks from infectious and pathogenic microorganisms
 - b. Identification of waterborne microorganisms associated with recreational water illness
 - c. Children's risks from fecal contamination in recreational water: epidemiological study review
 - d. Analysis of outbreak data for waterborne pathogens associated with recreational water illness in children: ambient/surface waters in the U.S.
3. The Contractor shall utilize the draft analysis detailed in the B-04 task 6.1 status update memo, "QMRA approaches to evaluate risks to sensitive subpopulations and children's health."
4. The Contractor shall specifically address the following questions in the conduct of this assignment :
 - a. Is there evidence for increased risk/illness for children compared to adults and/or the general population from exposure (any body contact; swimming, wading, ingestion, hand to mouth contact) to fecal contamination?
 - b. If so, can this difference be accounted for in recreational water quality determinations as measured by fecal indicator bacteria (FIB)?

Background: A growing body of scientific knowledge has demonstrated that children may suffer disproportionately from environmental health risks and safety risks. These risks occur because 1) children's neurological, immunological, digestive, and other bodily systems are still developing; 2) children eat more food, drink more fluids, and breathe more air in proportion to their body weight than adults; 4) children's size and weight may diminish their protection from standard safety features; and 5) children's behavior patterns may make them more susceptible to accidents because they are less able to protect themselves.

The importance of identifying and assessing risks to children was made in Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risk¹, which states:

“to the extent permitted by law and appropriate, and consistent with the agency's mission, each Federal agency:

(a) shall make it a high priority to identify and assess environmental health risks and safety risks that may disproportionately affect children; and (b) shall ensure that its policies, programs, activities, and standards address disproportionate risks to children that result from environmental health risks or safety risks.

1-102. Each independent regulatory agency is encouraged to participate in the implementation of this order and comply with its provisions.”

The U.S. Environmental Protection Agency (EPA)'s Policy on Evaluating Risks to Children² :

“considers the risks to infants and children consistently and explicitly as a part of risk assessments generated during its decision making process, including the setting of standards to protect public health and the environment. To the degree permitted by available data in each case, the Agency will develop a separate assessment of risks to infants and children or state clearly why this is not done - for example, a demonstration that infants and children are not expected to be exposed to the stressor under examination.”

The US EPA's Office of Children's Health Protection³ conducts research and supports risk assessments to assess children's risks and susceptibility to environmental contaminants (chemicals, toxins, air pollutants). However, it not clear whether children suffer disproportionate exposures and health outcomes as a result of exposure to pathogens such as found in recreational surface waters. Few epidemiological data and quantitative risk assessments have explored children's risks from microbial contaminants found in water, limiting the ability to determine if children experience different responses to waterborne fecal indicators and pathogens, or develop illness rates as a result of recreational water contact in the United States. Risks in children have specifically not been explored separately, but they are included as part of the general populations in most epidemiological studies.

Under the auspices of the Clean Water Act, the Agency regulates recreational water, and sets numeric indicator bacteria criteria (*Escherichia coli*, Enterococci) in surface (ambient) waters used for the purpose of recreational water contact. The current

¹ Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks. http://yosemite.epa.gov/oehp/ochpweb.nsf/content/whatwe_executiv.htm

² Policy on Evaluating Health Risks to Children. <http://www.epa.gov/osa/spc/pdfs/memohlth.pdf>

³ The Office of Children's Health Protection. http://yosemite.epa.gov/oehp/ochpweb.nsf/content/whatwe_executiv.htm

recreational water criteria were designed to protect swimmers (in general) from illnesses due to exposure to pathogens in recreational waters. The criteria developed in 1986 were mainly based on enumerations of fecal indicator bacteria (FIB) using culture-based methods. EPA is committed to develop new recreational water quality criteria for all water body types by 2012 and will address potentially disproportionate risks to children in the criteria development process.

Epidemiology studies have been conducted to describe and quantify the health effects associated with exposure to contaminated recreational waters. The primary goal of most of these studies has been to evaluate associations between measures of microbial water quality (usually quantified by measuring fecal indicator bacteria) and swimming-associated illness.

To address this issue, variations of two basic study designs have been used. For the purposes of this Work Assignment, these study designs are referred to as the "cohort" and the "randomized" design. The cohort design was used in the EPA epidemiology studies. The U.S. EPA, in collaboration with the Centers for Disease Control and Prevention have undertaken The National Epidemiological and Environmental Assessment of Recreational (NEEAR) Water Study to investigate human health effects and rapid water quality methods associated with recreational water use. A main goal of the NEEAR study is to determine how new ways of measuring fecal pollution can be used effectively to protect swimmers' health. The randomized design has been used in studies in Europe.

The approach of these designs differs in several critical aspects, some of which are summarized briefly below.

Swimmer/non-swimmer assignment:

The randomized design assigns "swimming" and non-swimming status by randomly assigning participants to each exposure group. The cohort design uses observed and self-reported swimming status. In the randomized design, swimmers are asked to swim completing specific activities such as immersing their head and/or staying in the water for a minimum amount of time at a designated position. In the cohort design, locations and swimming are assessed by interviewer and self-report.

Target population:

The EPA NEEAR cohort studies target the beach going population as their target population sample, and population of interest. Randomized trials often recruit subjects from nearby communities. Due to ethical issues, many randomized trial studies restrict their enrollment to adults 18 and over.

Water quality assessment and exposure assignment:

The randomized study usually attempts to assign individual exposures by intensively characterizing the water quality where an individual swimmer is exposed. However, there are known sampling and matrix issues with assigning water quality, as measured by fecal indicator bacteria, to individual swimmers.

Detection of indicator bacteria does not necessarily track the occurrence or distribution of pathogens that may or may not be present in the water column. Water quality in a cohort study is usually characterized by collecting samples in a fixed layout to assess average water quality over a given time/space dimension.

Other differences:

Because the cohort design is less intensive with regard to resources and investigator involvement, usually more subjects are enrolled over a wider range of days and environmental conditions. The EPA NEEAR Water Study has focused on FIB measured by novel and rapid analytical methods; whereas all published randomized designs have relied on traditional methods and approaches in measuring indicator bacteria.

Quality Assurance: The tasks in this PWS requires the use of secondary data/analyses and fall under the scope of the approved contract-level QAPP. Consistent with the Agency's quality assurance (QA) requirements, the contractor must assure the quality and analyses of the secondary data and other data collected to be used under this PWS.

The Contractor shall discuss with the EPA WAM if any of the specific work assignment tasks are not readily covered under the approved QAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a WA-specific QAPP supplement, which must be approved by the EPA before activities covered by the additional QA language begin under this PWS.

Statement of Work: The scope in this PWS will fall under the following task areas:

Task 1: Work Plan and monthly progress reports (MPR)

Task Area 1.1. Work Plan

The contractor shall develop a work plan to address all tasks in this work assignment. The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If a subcontractor(s) is proposed and subcontractors are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

Task Area 1.2. Monthly Progress Reports

This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoiced LOE and costs delineated by the tasks in this WA. The Contractor shall provide the EPA WAM with weekly

updates detailing progress. That updates shall be provided every Friday via email.

Travel: No contractor travel outside of the Washington, D.C. metro area is anticipated for this task.

Task Area 1.3. Information Quality Guidelines

The Contractor shall ensure the products developed under this PWS comply with the EPA Information Quality Guidelines and shall complete the Checklist for Influential Information as needed for each deliverable from this work assignment as they may be used in Agency decision-making and/or will be publicly available documents. The EPA WAM will provide the checklist to the Contractor. The Contractor shall provide a memorandum describing how the planned product(s) developed meet EPA's Information Quality Guidelines checklist. As part of that memo, the Contractor shall document the quality assurance procedures it used in developing the deliverables under this Work Assignment. The Contractor shall provide the memo at the time it delivers the Final Report under Task 2.1. As requested by the EPA WAM, the Contractor shall have a teleconference with the EPA WAM to discuss the Guidelines and the Contractor's role in completing the checklist.

Task Area 2: Project Reports

Task Area 2.1. Preparation of EPA report detailing results

The Contractor prepared and submitted a draft report for EPA technical review under this Task in the previous contract year detailing the information collected and analyzed for the evaluation of human health risks to children from recreational exposure to fecal contamination. The report was under review at the close of the previous contract year.

The Contractor shall revise the report based on the comments submitted by the EPA WAM and discuss options for addressing the comments with the EPA WAM once the Contractor has had a chance to review them. The Contractor shall also prepare effective communication materials to accompany the draft report for use in internal and eventually external communication efforts (see Task 3).

The report may undergo multiple edits and the Contractor shall respond to the EPA WAM comments. This document will need to be formatted as requested by the EPA WAM. The Contractor shall incorporate comments on any draft deliverables from the EPA WAM. Also, the Contractor shall update information in the report as needed to capture any developments related to ongoing studies. The report shall be compliant with Section 508 of the Rehabilitation Act when finalized and submitted (see <http://www.epa.gov/accessibility/index.htm>).

Task Area 2.2. Preparation of Report of External Scientific Peer Review

The Contractor shall prepare and submit a version of the final report based on the deliverable under Task 2.1 that would be suitable for external scientific peer

review. This task is subsequent to task 2.1. The Contractor shall submit a draft to the EPA WAM for Agency clearance. When all Agency comments have been addressed, that version may be submitted for peer review. The venue for the peer review is currently undetermined. The Contractor shall address peer reviewer comments in conjunction with the EPA WAM. This document will need to be formatted for publication as requested by the EPA WAM.

Travel: No contractor travel outside of the Washington, D.C. metro area is anticipated for this task.

Task Area 3: *Communication materials*

As specified in the above methodology section, the Contractor shall prepare, in conjunction with the EPA WAM, materials to assist in communicating the complex technical aspects of the project results to both non-technical and technical (but not academic) audiences (both internal and external to the Agency). These materials will most likely consist of synopses, executive summaries, Q&As, presentation slides, etc. and each may be aimed at a particular audience or tailored for the communication need. The Contractor shall coordinate with the EPA WAM on the scope and nature of these materials for specific audiences.

Task Area 4: *General Project Support*

The Contractor shall, based on technical direction given by the EPA WAM, provide support in preparing interim project update and/or other materials for internal and external audiences. These may include, but are not limited to, short briefing documents and PowerPoint presentations. The contractor may also be directed to participate in and/or conduct briefings and/or present at meetings. It is estimated that this task should not require more than 5 – 10 % of the total LOE allotted to this work assignment.

One of the outcomes of the project planning meeting detailed in Task 2.1 may be the identification of data or analysis gaps, particularly in regards to the QMRA analysis. For example, the finalized analysis of the NEEAR marine data was not completed at the time of the conduct of the QMRA under B-04, task 6. Although the final analysis of that data did not show a significant difference in illness response between children 12 and under and the general population, using this combined dataset may be helpful for the discussion of the QMRA portion of the deliverables under tasks 2.1 and 2.2. Should such analyses be identified as important based on the outcome of the project planning meeting, the EPA WAM will provide technical direction to ICF.

The Contractor shall plan on attending one presentation at EPA HQ at the draft report stage to discuss findings. All appropriate clearances and approvals required by Agency policy in support of any and all meetings shall be obtained by the EPA PO as needed and provided to the Contracting Officer. Work under meeting-

related activities and expenses shall not occur until this approval is obtained and provided by the PO.

Schedule and Deliverables:

| Task No. | Milestones/Deliverable* | Schedule |
|-----------------|---|--|
| 1 | 1.1 Workplan | Within 15 calendar days of receipt of WA |
| 1 | 1.3 Information Quality Guidelines | Submitted with final deliverables |
| 2 | *2.1 Draft report for EPA review | Draft submitted |
| 2 | 2.1 Respond to EPA reviewer comments | Within 2 weeks of receiving EPA WAM comments |
| 2 | 2.1 Submit final report to EPA | Within 2 weeks of addressing comments |
| 2 | 2.2 Submit draft report for EPA review | TBD based on outcome of Task 2.1 |
| 2 | 2.2 Respond to EPA reviewer comments | Within 2 weeks of receiving EPA WAM comments |
| 2 | 2.2 Submit final report to EPA for peer review clearance | Within 2 weeks of addressing comments |
| 3 | Prepare risk communication presentation materials for technical and non-technical audiences | TBD by technical direction |
| 4 | General project support | TBD by technical direction |

* Report was on schedule to be submitted to EPA by the end of previous contract year when this work assignment was being prepared. The milestone was included here to provide a starting point for Task 2 activities.

Task Knowledge and Skills Required: The Contractor shall have expertise in preparing the materials associated with this work assignment and be knowledgeable with the various fields of discipline discussed. The Contractor shall also be proficient in R programming and other relevant statistical tools. The Contractor shall have practical experience in environmental microbiology, epidemiology, and statistical methods and analysis and have advanced credentials in statistics or environmental engineering. The Contractor shall be familiar with the different programs under the CWA, use of water quality monitoring, determination of human exposure to environmental contaminant sources, and gastrointestinal (or other) disease endpoints, applications of epidemiological data, and other factors associated with needs in recreational water quality and CWA 304(a) criteria development.

The Contractor shall also be able to communicate the study outcomes and recreational outbreak data to a non-technical audience.

General Requirements of the Work Assignment and Schedule:

Due Dates: The Contractor shall provide due dates that are mutually acceptable with the EPA WAM. The Contractor shall notify the EPA WAM in advance, if a due date will not be met and request a revised date.

Delays: The Contractor shall make every effort to ensure there are no Contractor-caused delays. If a delay is inevitable, it is the Contractor's responsibility to notify the EPA WAM at the first sign of said delay. A revised schedule will then be worked out.

Draft Documents: The Contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. EPA WAM will provide comments on draft submissions prior to submission of final documents.

Final Documents: The Contractor shall submit final documents both electronically and in hardcopy to EPA WAM.

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| EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment | | Work Assignment Number 2-08 | | | | | | | | |
| | | <input type="checkbox"/> Other <input type="checkbox"/> Amendment Number: | | | | | | | | |
| Contract Number EP-C-11-005 | | Contract Period 01/01/2011 To 12/31/2013 Base Option Period Number 2 | | | | | | | | |
| Title of Work Assignment/SF Site Name Activities to support AWQC | | | | | | | | | | |
| Contractor ICF INCORPORATED, L.L.C. | | Specify Section and paragraph of Contract SOW see PWS | | | | | | | | |
| Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval | | Period of Performance From 01/01/2013 To 12/31/2013 | | | | | | | | |
| Comments: | | | | | | | | | | |
| <div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund <div style="text-align: center;">Accounting and Appropriations Data</div> <input checked="" type="checkbox"/> Non-Superfund </div> | | | | | | | | | | |
| Note: To report additional accounting and appropriations data use EPA Form 1900-69A. | | | | | | | | | | |
| SFO (Max 2) <input type="checkbox"/> | | | | | | | | | | |
| Line | DCN (Max 6) | Budget/FY (Max 4) | Appropriation Code (Max 6) | Budget Org/Code (Max 7) | Program Element (Max 9) | Object Class (Max 4) | Amount (Dollars) | (Cents) | Site/Project (Max 8) | Cost Org/Code (Max 7) |
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| Contract Period: 01/01/2011 To 12/31/2013 Cost/Fee: LOE: | | | | | | | | | | |
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| Work Plan / Cost Estimate Approvals | | | | | | | | | | |
| Contractor WP Dated: Cost/Fee: LOE: | | | | | | | | | | |
| Cumulative Approved: Cost/Fee: LOE: | | | | | | | | | | |
| Work Assignment Manager Name Sharon Nappier _____ (Signature) (Date) | | | | | | | Branch/Mail Code: Phone Number 202-566-0740 FAX Number: | | | |
| Project Officer Name Shirley Harrison _____ (Signature) (Date) | | | | | | | Branch/Mail Code: Phone Number: 202-566-1107 FAX Number: | | | |
| Other Agency Official Name Shirley Harrison _____ (Signature) (Date) | | | | | | | Branch/Mail Code: Phone Number: 202-566-1107 FAX Number: | | | |
| Contracting Official Name Sandra Stargardt-Licis _____ (Signature) (Date) | | | | | | | Branch/Mail Code: Phone Number: 513-487-2006 FAX Number: | | | |

**PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-11-005
WORK ASSIGNMENT #2-08**

Title: Activities to support the development of Ambient Water Quality Criteria for Viruses

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E-mail: ravenscroft.john@epa.gov

Period of Performance: January 1, 2013 through December 31, 2013

Contractor SOW: 3.1, 3.3, 3.4, 3.6

****Note:** No CBI data will be needed in the course of this work assignment.

Background:

Human health ambient water quality criteria (AWQC) are numeric values limiting the amount of chemical or microbial agents present in our nation's waters. Human health criteria are developed under Section 304(a) of the Clean Water Act of 1972 and are designed to protect human health. Water quality criteria are developed by assessing the relationship between pollutants and their effect on human health and the environment. These criteria are used by states and Indian tribes to establish water quality standards and ultimately provide a basis for controlling discharges or releases of pollutants. EPA has published AWQC for bacteria. Historically EPA has based the bacteria criteria on fecal indicator bacteria (FIB). These organisms do not generally cause human illness themselves (that is, they are not human pathogens); rather, they are indicators of fecal contamination and therefore indicators of the potential presence of human pathogenic organisms.

The EPA is now interested in creating AQWC for viruses. EPA believes that these virus criteria must be scientifically sound, implementable for broad CWA purposes, and provide for improved public health protection.

Quality Assurance:

The tasks in this work assignment (WA) require the use of secondary data/analyses and fall under the scope of the approved contract-level QAPP. Consistent with the Agency's quality assurance (QA) requirements, the contractor must assure the quality and analyses of the secondary data and other data collected to be used under this work assignment.

The Contractor shall discuss with the EPA WAM if any of the specific work assignment tasks are not readily covered under the approved contract-level QAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a WA-specific QAPP supplement, which must be approved by the EPA WAM before activities covered by the additional QA language begin under this work assignment.

Performance Work Statement (PWS): The scope of work in this work assignment will fall under the following task areas:

TASK 1 – Workplan and Monthly Progress Reports

Task Area 1.1. Work Plan

The contractor shall develop a detail work plan and cost estimate for each task outlined in this work assignment. The plan should contain, but not limited to, work-flowchart, elaborate schedule (task-wise), staffing plan and qualifications of proposed staff, budget for each task and level of effort (LOE). Prior to the submission of the work plan, the contractor shall consult with the EPA WAM via conference call to mitigate any potential issues that need clarifications. The contractor shall include information on plans to manage work and control contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

This task also includes monthly progress and financial reports. The monthly Progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs' broken out by the tasks in this WA.

Task 1.2 Information Quality Guidelines

The Contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines and shall complete the Checklist for Influential Information as needed for each deliverable from this work assignment as the may be used in Agency decision-making and/or will be publicly available documents. The EPA WAM will provide the checklist to the Contractor. The Contractor shall provide a memorandum describing how the planned product(s) developed meet EPA's Information Quality Guidelines checklist. As part of that memo, the Contractor shall document the quality assurance procedures it used in developing the deliverables under this Work Assignment. The Contractor shall provide the memo at the time it delivers the Final Summary Report. The Contractor shall have a teleconference with the EPA WAM to discuss the Guidelines and the Contractor's role in completing the checklist.

Task 2 - Re-evaluate, Update, and Finalize the *Methodology for Deriving Microbial AWQC for Recreational Designated Uses for the Protection of Human Health*

In 2006, EPA drafted the recommended *Methodology for Deriving Microbial AWQC for Recreational Designated Uses for the Protection of Human Health*. The Microbial Methodology is guidance for scientific human health assessments used by EPA to develop, publish, and revise, recommended criteria for water quality accurately reflecting the latest scientific knowledge. The recommended criteria would serve states' and tribes' needs in their development of water quality standards.

The Contractor shall finalize the *Methodology for Deriving Microbial AWQC for Recreational Designated Uses for the Protection of Human Health* for publication. The most recent document underwent External Peer Review in 2006. However, the Contractor shall update and re-evaluate the document to reflect the most recent draft *Microbiological Risk Assessment (MRA) Tools, Methods, and Approaches for Water Media* and the current scientific literature. Process steps for re-evaluating, updating, and finalizing the document will be provided through Technical Direction.

TASK 3 – Literature Reviews

Task Area 3.1 Bacteriophage Literature Review

This task is a continuation of previous efforts under WA 1-08. The contractor shall conduct a bacteriophage literature review to identify important research that support the development of future bacteriophage criteria. In addition to 304(a) criteria, the review should address the potential usefulness of bacteriophages as indicators in various media, such as wastewater effluent, biosolids, and in shellfish waters. EPA anticipates there will be several internal reviews of the document. The contractor shall assist in incorporating comments and edits and deliver a final literature review product. The Contractor shall make the final document 508 compliant.

Task Area 3.2 Norovirus: Human Health Assessment

This task is a continuation of previous efforts under WA 1-08. The contractor shall conduct an EPA Human Health Assessment document or documents for noroviruses and in the process identify important research that will support the development of future virus criteria. EPA anticipates there will be several internal reviews of the Human Health Assessment. The contractor shall assist in incorporating comments and edits and deliver a final Human Health Assessment product. The Contractor shall make the final document 508 compliant.

TASK 4 – Ambient Water Quality Criteria Bacteriophages and other Viruses

Task Area 4.1 Scope of the Criteria Documents

This task will require the Contractor to assist scoping the AWQC for Viruses for recreational designated uses. Viruses of immediate interest include, but are not limited to, bacteriophage, norovirus, and enterovirus. EPA is considering one criterion document for bacteriophages and another for pathogenic viruses, such as enteroviruses and noroviruses. The Contractor shall assist in drafting an outline of pathogen criteria for viral indicators and pathogenic viruses and identifying the needs of the criterion documents.

Task Area 4.2 Derivation of the Criteria Values

Drawing on the draft *Microbiological Risk Assessment (MRA) Tools, Methods, and Approaches for Water Media*, the *Methodology for Deriving Microbial AWQC for Recreational Designated Uses for the Protection of Human Health*, and any other materials EPA deems appropriate, the Contractor shall develop AWQC values for the viruses of interest. Specific viruses and the order of importance will be provided through Technical Direction.

Task Area 4.3 Develop Criterion Document Drafts

The Contractor shall provide draft documents of the AWQC for viruses. Again, specific viruses and the order of importance will be provided through Technical Direction. This task will be an ongoing effort for the period of performance of this work assignment and a series of drafts are expected.

Task Area 4.4 Prepare and submit Final AWQC Criteria for Bacteriophage and other Viruses

The Contractor shall prepare and submit a Final RWQC document. This document will need to be 508 Compliant and formatted as directed by the EPA WAM.

Task Area 4.5. Prepare briefing materials and other supporting documents pertaining to the Virus Criteria documents

Briefing materials and other supporting documents will be needed during the virus criteria development process. The Contractor shall aid in the development of any materials or presentations for these purposes.

Task Area 5 - General Project Support

The Contractor shall, based on technical direction given by the EPA WAM, provide support in preparing interim project update and other materials for internal and external audiences. These may include, but are not limited to, short briefing documents and PowerPoint presentations. The Contractors may be requested to participate in and/or conduct briefings. A weekly update call with the EPA WAM will be required for this work assignment, as needed.

Some meetings may require Contractor support and/or attendance for note-taking, presentations, and meeting preparation materials. Additionally, ODCs have been added for travel for up to 2 trips. Details on travel dates and locations will be provided by the EPA WAM through technical direction, as further information becomes available.

Travel: Travel may be needed as deemed necessary by the EPA WAM. No contractor travel outside of the Washington, D.C. metro area is required.

| Task No. | Deliverable | Schedule |
|----------|--|---|
| 1 | 1.1 Work Plan | Within <u>15</u> business days of receipt of WA |
| 2 | 2.0 Re-evaluate, update, and finalize the <i>Methodology for Deriving Microbial Ambient Water Quality Criteria for Recreational Designated Uses for the Protection of Human Health</i> | TBD |
| 3 | 3.1 Bacteriophage Literature Review - DRAFT | February 1, 2013 |
| 3 | 3.1 Bacteriophage Literature Review - FINAL | June 1, 2013 |
| 3 | 3.2 Norovirus: Human Health Assessment - DRAFT | March 1, 2013 |
| 3 | 3.2 Norovirus: Human Health Assessment - FINAL | July 1, 2013 |
| 4 | 4.1 Scope of the Criteria documents | TBD |

| | | |
|---|---|-----|
| 4 | 4.2 Derivation of the Criteria Values | TBD |
| 4 | 4.3 Develop Criteria Document Drafts | TBD |
| 4 | 4.4 Submit Final AWQC Criterion for Viruses | TBD |
| 4 | 4.5 Prepare briefing materials and other supporting documents | TBD |
| 5 | 5.0 General Project Support | TBD |

Quality Assurance: Tasks 2-4 in this work assignment require the use of secondary data. An approved project-specific QAPP has already been approved, under work assignment B-08.

The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1 and should follow the attachment titled, QAPP Requirements for projects using secondary data.

Knowledge and Skills Required: Contractor shall have expertise in preparing the aforementioned materials and be knowledgeable with the various fields of discipline discussed in this work assignment. The Contractor shall have practical experience in conducting microbial risk assessments and have advanced credentials in environmental microbiology and/or environmental engineering. The Contractor shall be familiar with the use of fecal indicator organisms, microbiological analytical methods (including molecular techniques), water monitoring applications of epidemiological data, determination of human exposure to environmental contaminant sources, and gastrointestinal disease endpoints.

General Requirements of the Work Assignment and Schedule:

Due Dates: The Contractor shall provide due dates that are mutually acceptable with the EPA WAM. The Contractor shall notify the EPA WAM in advance, if a due date will not be met and request a revised date.

Delays: The Contractor shall make every effort to ensure there are no Contractor-caused delays. If a delay is inevitable, it is the Contractor's responsibility to notify the EPA WAM at the first sign of said delay. A revised schedule will then be worked out.

Draft Documents: The Contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. EPA WAM will provide comments on draft submissions prior to submission of final documents.

Final Documents: The Contractor shall submit final documents both electronically and in hardcopy to EPA WAM.

**MEETINGS, CONFERENCES, TRAINING EVENTS, AWARD CEREMONIES
AND RECEPTIONS:**

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA PO as needed and provided to the Contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the EPA PO.

| | | | | | | | |
|---|----------------|---|-------------------------------|---|---|--|--|
| EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment | | | | | | Work Assignment Number 2-08 | |
| | | | | | | <input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000001 | |
| Contract Number EP-C-11-005 | | Contract Period 01/01/2011 To 12/31/2013 Base Option Period Number 2 | | | Title of Work Assignment/SF Site Name AWQC for Pathogens | | |
| Contractor ICF INCORPORATED, L.L.C. | | | | Specify Section and paragraph of Contract SOW | | | |
| Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval | | | | | | Period of Performance From 01/01/2013 To 12/31/2013 | |
| Comments: | | | | | | | |
| <input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund | | | | | | | |
| Note: To report additional accounting and appropriations data use EPA Form 1900-69A. | | | | | | | |
| SFO (Max 2) <input type="checkbox"/> | | | | | | | |
| Line | DCN (Max 6) | Budget/FY (Max 4) | Appropriation Code (Max 6) | Budget Org/Code (Max 7) | Program Element (Max 9) | Object Class (Max 4) | Amount (Dollars) (Cents) Site/Project (Max 8) Cost Org/Code (Max 7) |
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| Authorized Work Assignment Ceiling | | | | | | | |
| Contract Period: | | Cost/Fee: | | LOE: | | | |
| 01/01/2011 To 12/31/2013 | | | | | | | |
| This Action: | | | | | | | |
| Total: | | | | | | | |
| Work Plan / Cost Estimate Approvals | | | | | | | |
| Contractor WP Dated: | | Cost/Fee: | | LOE: | | | |
| Cumulative Approved: | | Cost/Fee: | | LOE: | | | |
| Work Assignment Manager Name Sharon Nappier _____ (Signature) (Date) | | | | | | Branch/Mail Code: Phone Number 202-566-0740 FAX Number: | |
| Project Officer Name Shirley Harrison _____ (Signature) (Date) | | | | | | Branch/Mail Code: Phone Number: 202-566-1107 FAX Number: | |
| Other Agency Official Name _____ (Signature) (Date) | | | | | | Branch/Mail Code: Phone Number: FAX Number: | |
| Contracting Official Name Sandra Stargardt-Licis _____ (Signature) (Date) | | | | | | Branch/Mail Code: Phone Number: 513-487-2006 FAX Number: | |

**PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-11-005
WORK ASSIGNMENT #2-08 Amd 1**

Title: Activities to support the development of Ambient Water Quality Criteria for Pathogens

Work Assignment Manager: Sharon Nappier (Mail Code 4304T)
Health and Ecological Criteria Division
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Phone (202) 566-0740
E-mail: nappier.sharon@epa.gov

Alternate WAM: John Ravenscroft (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Phone (202) 566-1101
E-mail: ravenscroft.john@epa.gov

Period of Performance: Performance Work Statement (Amd) thru December 31, 2013

Purpose of Amendment: The purpose of this amendment is to add LOE hours and funding for the following Tasks below. Additionally, ODCs have been added for travel for up to 2 trips. Details on travel dates and locations will be provided by the EPA WAM through technical direction, as further information becomes available. The contractor shall submit a cost estimate for this amendment

TASK 1 – Workplan and Monthly Progress Reports -- *No changes - task remains the same*

Task 2 - Re-evaluate, Update, and Finalize the *Methodology for Deriving Microbial Ambient Water Quality Criteria (AWQC) for Recreational Designated Uses for the Protection of Human Health*

No changes- task remains the same

TASK 3 – Literature Reviews

Additional funds will be used to support both Tasks 3.1 and 3.2, the drafting and finalizing of literature reviews and human health assessment documents to support future ambient water quality criteria for viruses. In the near-term, we are interested in evaluating bacteriophages and noroviruses.

Both literature reviews will likely undergo several internal reviews, drafts, and potentially external peer-review. The contractor shall be required to edit multiple versions, as needed.

TASK 4 – Ambient Water Quality Criteria Bacteriophages and other Viruses
Additional funds will go to support

Additional funds will go to support subtasks 4.1, 4.2, 4.3, and 4.4. Specifically they will be used to scope the criteria document, derive criteria values, and develop a criterion draft for public comment and peer-review.

No additional changes to Task 4– other sub-tasks remain the same.

Task Area 5 - General Project Support

ODCs have been added for travel for up to 2 trips. Details on travel dates and locations will be provided by the EPA WAM through technical direction, as further information becomes available.

| Task No. | Deliverable | Schedule |
|----------|--|--|
| 1 | 1.1 Work Plan | Within 10 business days of receipt of WA |
| 2 | 2.0 Re-evaluate, update, and finalize the <i>Methodology for Deriving Microbial Ambient Water Quality Criteria for Recreational Designated Uses for the Protection of Human Health</i> | TBD |
| 3 | 3.1 Bacteriophage Literature Review - DRAFT | March 15, 2013 |
| 3 | 3.1 Bacteriophage Literature Review – FINAL for Peer-Review | June 1, 2013 |
| 3 | 3.2 Norovirus: Human Health Assessment - DRAFT | April 1, 2013 |
| 3 | 3.2 Norovirus: Human Health Assessment – FINAL for Peer-Review | June 15, 2013 |
| 4 | 4.1 Scope of the Criteria documents | TBD |
| 4 | 4.2 Derivation of the Criteria Values | TBD |
| 4 | 4.3 Develop Criteria Document Drafts | TBD |
| 4 | 4.4 Submit Final AWQC Criterion for Viruses | TBD |
| 4 | 4.5 Prepare briefing materials and other supporting documents | TBD |
| 5 | 5.0 General Project Support | TBD |

Quality Assurance: same as the original PWS.

Knowledge and Skills Required: same as the original PWS.

| | | | | | | | |
|---|----------------|---|-------------------------------|---|----------------------------|--|--|
| EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment | | | | | | Work Assignment Number 2-08 | |
| | | | | | | <input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000002 | |
| Contract Number EP-C-11-005 | | Contract Period 01/01/2011 To 12/31/2013 | | | | Title of Work Assignment/SF Site Name | |
| | | Base Option Period Number 2 | | | | AWQC for viruses | |
| Contractor ICF INCORPORATED, L.L.C. | | | | Specify Section and paragraph of Contract SOW 3.1, 3.3, 3.4, 3.6 | | | |
| Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval | | | | Period of Performance From 01/01/2013 To 12/31/2013 | | | |
| Comments: | | | | | | | |
| <input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund | | | | | | | |
| SFO (Max 2) <input type="checkbox"/> Note: To report additional accounting and appropriations data use EPA Form 1900-69A. | | | | | | | |
| Line | DCN (Max 6) | Budget/FY (Max 4) | Appropriation Code (Max 6) | Budget Org/Code (Max 7) | Program Element (Max 9) | Object Class (Max 4) | Amount (Dollars) (Cents) Site/Project (Max 8) Cost Org/Code (Max 7) |
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| Contract Period: 01/01/2011 To 12/31/2013 | | Cost/Fee: | | LOE: | | | |
| This Action: | | | | | | | |
| Total: | | | | | | | |
| Work Plan / Cost Estimate Approvals | | | | | | | |
| Contractor W/P Dated: | | | | Cost/Fee: | | LOE: | |
| Cumulative Approved: | | | | Cost/Fee: | | LOE: | |
| Work Assignment Manager Name Sharon Nappier | | | | | | Branch/Mail Code: | |
| _____ (Signature) (Date) | | | | | | Phone Number 202-566-0740 | |
| | | | | | | FAX Number: | |
| Project Officer Name Shirley Harrison | | | | | | Branch/Mail Code: | |
| _____ (Signature) (Date) | | | | | | Phone Number: 202-566-1107 | |
| | | | | | | FAX Number: | |
| Other Agency Official Name Shirley Harrison | | | | | | Branch/Mail Code: | |
| _____ (Signature) (Date) | | | | | | Phone Number: 202-566-1107 | |
| | | | | | | FAX Number: | |
| Contracting Official Name Sandra Stargardt-Licis | | | | | | Branch/Mail Code: | |
| _____ (Signature) (Date) | | | | | | Phone Number: 513-487-2006 | |
| | | | | | | FAX Number: | |

**PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-11-005
WORK ASSIGNMENT #2-08 Amd 2**

Title: Activities to support the development of Ambient Water Quality Criteria for Pathogens

Work Assignment Manager: Sharon Nappier (Mail Code 4304T)
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E-mail: nappier.sharon@epa.gov

Alternate WAM: John Ravenscroft (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Phone (202) 566-1101
E-mail: ravenscroft.john@epa.gov

Period of Performance: WA Amendment Issuance thru December 31, 2013

Purpose of Amendment: The purpose of this amendment is to add additional funding for continual support for the existing Task 2 thru Task 5. Additionally, ODCs have been added for travel for up to 2 trips. Details on travel dates and locations will be provided by the EPA WAM through technical direction, as further information becomes available. The contractor shall submit a revised cost estimate for this amendment.

TASK 1 – Workplan/Monthly Progress Reports -- *No changes – task remains the same.*

Task 2 - Re-evaluate, Update, and Finalize the Methodology for Deriving Microbial Ambient Water Quality Criteria (AWQC) for Recreational Designated Uses for the Protection of Human Health

No changes- task remains the same.

TASK 3 – Literature Reviews

Additional funds will be used to support both Tasks 3.1 and 3.2, the drafting and finalizing of literature reviews and human health assessment documents to support future ambient water quality criteria for viruses. In the near-term, we are interested in evaluating bacteriophages, noroviruses and adenoviruses.

All three literature reviews will likely undergo several internal reviews, drafts, and potentially external peer-review. Contractor will be required to edit multiple versions, as needed.

TASK 4 – Ambient Water Quality Criteria Bacteriophages and other Viruses

Additional funds will go to support

Additional funds will go to support subtasks 4.1, 4.2, 4.3, and 4.4. Specifically they will be used to scope the criteria document, derive criteria values, and develop a criterion draft for public comment and peer-review.

No additional changes to Task 4– other sub-tasks remain the same.

Task Area 5 - General Project Support

ODCs have been added for travel for up to 2 trips. Details on travel dates and locations will be provided by the EPA WAM through technical direction, as further information becomes available.

| Task No. | Deliverable | Schedule |
|----------|--|--|
| 1 | 1.1 Work Plan | Within 10 business days of receipt of WA |
| 1 | 1.2 Monthly Progress Reports | Monthly (the 20th of every month) |
| 2 | 2.0 Re-evaluate, update, and finalize the <i>Methodology for Deriving Microbial Ambient Water Quality Criteria for Recreational Designated Uses for the Protection of Human Health</i> | TBD |
| 3 | 3.1 Bacteriophage Literature Review - DRAFT | Two weeks after receipt draft from EPA. |
| 3 | 3.1 Bacteriophage Literature Review – FINAL for Peer-Review | Two weeks after receipt draft from EPA. |
| 3 | 3.2 Norovirus: Human Health Assessment - DRAFT | Two weeks after receipt draft from EPA |
| 3 | 3.2 Norovirus: Human Health Assessment – FINAL for Peer-Review | Two weeks after receipt draft from EPA |
| 4 | 4.1 Scope of the Criteria documents | TBD |
| 4 | 4.2 Derivation of the Criteria Values | TBD |
| 4 | 4.3 Develop Criteria Document Drafts | TBD |
| 4 | 4.4 Submit Final AWQC Criterion for Viruses | TBD |
| 4 | 4.5 Prepare briefing materials and other supporting documents | TBD |
| 5 | 5.0 General Project Support | TBD |

Quality Assurance: same as the original PWS.

Knowledge and Skills Required: same as the original PWS.

| | | | | | | | | | | |
|---|--|---|-------------------------------|----------------------------|----------------------------|-------------------------------|------------------|---------|-------------------------|--------------------------|
| EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment | | Work Assignment Number 2-09 <input type="checkbox"/> Other <input type="checkbox"/> Amendment Number: | | | | | | | | |
| Contract Number EP-C-11-005 | Contract Period 01/01/2011 To 12/31/2013 Base Option Period Number 2 | Title of Work Assignment/SF Site Name Human Health Assessment: Crypt | | | | | | | | |
| Contractor ICF INCORPORATED, L.L.C. | | Specify Section and paragraph of Contract SOW 2.2, 3.1.6, 3.1.8 | | | | | | | | |
| Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval | | Period of Performance From 01/01/2013 To 12/31/2013 | | | | | | | | |
| Comments: | | | | | | | | | | |
| <input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund | | | | | | | | | | |
| SFO (Max 2) <input type="checkbox"/> Note: To report additional accounting and appropriations data use EPA Form 1900-69A. | | | | | | | | | | |
| Line | DCN (Max 6) | Budget/FY (Max 4) | Appropriation Code (Max 6) | Budget Org/Code (Max 7) | Program Element (Max 9) | Object Class (Max 4) | Amount (Dollars) | (Cents) | Site/Project (Max 8) | Cost Org/Code (Max 7) |
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| Authorized Work Assignment Ceiling | | | | | | | | | | |
| Contract Period: 01/01/2011 To 12/31/2013 | | Cost/Fee: | | | | LOE: | | | | |
| This Action: | | | | | | | | | | |
| Total: | | | | | | | | | | |
| Work Plan / Cost Estimate Approvals | | | | | | | | | | |
| Contractor WP Dated: | | Cost/Fee: | | | | LOE: | | | | |
| Cumulative Approved: | | Cost/Fee: | | | | LOE: | | | | |
| Work Assignment Manager Name Shamima Akhter | | | | | | Branch/Mail Code: | | | | |
| _____ (Signature) (Date) | | | | | | Phone Number 202-566-0000 | | | | |
| | | | | | | FAX Number: | | | | |
| Project Officer Name Shirley Harrison | | | | | | Branch/Mail Code: | | | | |
| _____ (Signature) (Date) | | | | | | Phone Number: 202-566-1107 | | | | |
| | | | | | | FAX Number: | | | | |
| Other Agency Official Name Shirley Harrison | | | | | | Branch/Mail Code: | | | | |
| _____ (Signature) (Date) | | | | | | Phone Number: 202-566-1107 | | | | |
| | | | | | | FAX Number: | | | | |
| Contracting Official Name Sandra Stargardt-Licis | | | | | | Branch/Mail Code: | | | | |
| _____ (Signature) (Date) | | | | | | Phone Number: 513-487-2006 | | | | |
| | | | | | | FAX Number: | | | | |

**PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-11-005
WORK ASSIGNMENT # 2-09**

Title: Human Health Assessment: *Cryptosporidium* and *Giardia* in drinking and ambient water .

Work Assignment Manager: Shamima Akhter (Mail Code 4304T)
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Alternate WAM: John Ravenscroft (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Phone (202) 566-1101
E-mail: ravenscroft.john@epa.gov

Period of Performance: January 1, 2013 through December 31, 2013

Contractor SOW: 2.2, 3.1.6, and 3.1.8

Background:

The mission of the U.S. Environmental Protection Agency's (EPA) Office of Water is to protect public health and the environment from adverse effects of pollutants (e.g., toxic chemicals and microbial pathogens) in ambient water, drinking water, wastewater, sewage sludge and sediments. The Safe Drinking Water Act (SDWA) requires the EPA to regulate disease-causing organisms (pathogens) and toxic chemicals in drinking water.

The Safe Drinking Water Act requires the U.S. Environmental Protection Agency (EPA) to publish regulations to control disease-causing organisms (pathogens) and hazardous chemicals in drinking water. One of the regulations published by EPA to control pathogens is known as the Surface Water Treatment Rule (54 FR 27486; June 29, 1989). The purpose of the Long Term 2 (LT2) rule is to reduce illness linked with the contaminant *Cryptosporidium*, *Giardia* and other disease-causing microorganisms in drinking water. Under the LT 2 Rule, *Cryptosporidium* oocysts at or below 0.075 oocysts/liter are considered the maximum value under which conventional drinking water treatment is expected to be capable of providing protection of consumers drinking up to 1.2 liters of water per day. Under the Safe Drinking Water Act's Surface Water Treatment Rule (further referred to as the Rule) *Giardia* cyst Maximum Contaminant Level Goal (MCLG) levels are set at "0" for treated water. In order to meet this

requirement, *Giardia* cyst removal by conventional drinking water treatment must be able to reduce cyst levels by 3 orders of magnitude (3 logs) from source waters to insure protection of consumers drinking up to 2.0 liters of water per day.

Cryptosporidium is a significant concern in drinking water because it contaminates surface waters used as drinking water sources, it is resistant to chlorine and other disinfectants, and it has caused waterborne disease outbreaks. Consuming water with *Cryptosporidium*, a contaminant in drinking water sources, can cause gastrointestinal illness (e.g., diarrhea, vomiting, cramps) and other health risks, which may be severe in people with weakened immune systems (e.g., infants and the elderly) and sometimes fatal in people with severely compromised immune systems (e.g., cancer and AIDS patients).

Cryptosporidium oocysts are common and widespread in ambient water and can persist for months in this environment. The dose that can infect humans is low, and a number of waterborne disease outbreaks caused by this protozoan have occurred in the U.S., most notably in Milwaukee, where an estimated 400,000 people became ill. The healthy people recover within several weeks after becoming ill, but illness may persist and contribute to death in those whose immune systems have been seriously weakened (e.g., AIDS patients). Drugs effective in preventing or controlling this disease are not yet available. The public health concern is worsened by the resistance of *Cryptosporidium* to water disinfection practices by chlorination, although oocysts can be inactivated by ozone and ultraviolet irradiation. However, a well-operated water filtration system is capable of removing at least 99 of 100 *Cryptosporidium* oocysts in the water. Monitoring for this organism in water is currently difficult and expensive.

The purpose of these documents is to serve as informal technical guidance to assist Federal, state, and local officials responsible for protecting public health when emergency spills or contamination situations occur.

Quality Assurance:

The tasks in this work assignment (WA) require the use of secondary data/analyses and fall under the scope of the approved contract-level QAPP. Consistent with the Agency's quality assurance (QA) requirements, the contractor must assure the quality and analyses of the secondary data and other data collected to be used under this work assignment.

The Contractor shall discuss with the EPA WAM if any of the specific work assignment tasks are not readily covered under the approved QAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a WA-specific QAPP supplement, which must be approved by the EPA WAM before activities covered by the additional QA language begin under this work assignment.

Performance Work Statement (PWS):

Task 1: Work plan and monthly progress reports

Task 1.1 Work Plan

The contractor shall develop a detail work plan and cost estimate for each task outlined in this work assignment. The plan should contain, but not limited to, work-flowchart, elaborate schedule (task-wise), staffing plan and qualifications of proposed staff, budget for each task and level of effort (LOE). Prior to the submission of the work plan, the contractor shall consult with the WAM via conference call to mitigate any potential issues that need clarifications. The contractor shall include information on plans to manage work and control contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs' broken out by the tasks in this WA.

Task 1.2 Information Quality Guidelines

The Contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines and shall complete the Checklist for Influential Information as needed for each deliverable from this work assignment as they may be used in Agency decision-making and/or will be publicly available documents. The EPA WAM will provide the checklist to the Contractor. The Contractor shall provide a memorandum describing how the planned product(s) developed meet EPA's Information Quality Guidelines checklist. As part of that memo, the Contractor shall document the quality assurance procedures it used in developing the deliverables under this Work Assignment. The Contractor shall provide the memo at the time it delivers the Final Summary Report. The Contractor shall have a teleconference with the EPA WAM to discuss the Guidelines and the Contractor's role in completing the checklist.

Task 2: Develop Health Assessment document: *Cryptosporidium*

2.2 Develop analysis plan and conduct exposure and dose response analysis

Historical technical data that was used to generate the LT2 Rule will be obtained from the EPA's Water Docket.

The health assessment document shall be comprised of a comprehensive review of published literatures on *Cryptosporidium* providing all relevant information, the general characteristics of this protozoan, its occurrence in human and animal populations and in

water, drinking water exposures, dose response, the health effects associated with *Cryptosporidium* infection are important features of the health assessment and all data of this nature should be captured from both US and foreign data bases. The EPA WAM will provide the *Outline for the drinking and ambient water health assessments* to the contractor. The contractor shall evaluate several different permutations of the available feeding study dose response information for various strains and their combination. The contractor shall also estimate dose based upon 1.2 and 2.0 liters of water/day.

The contractor shall coordinate with the EPA WAM in the collection of datasets for exposure and dose response from various sources for the analysis. Collection of datasets will be conducted such that the Office of Management and Budget (OMB) Information Collection Rule (ICR) will not be triggered.

2.3 Submit draft report of initial findings

The contractor shall prepare a draft *Cryptosporidium* health assessment document for EPA WAM review. The contractor shall insure that all factors that were applied to the health assessment are stated and are transparent throughout the document. The contractor shall include a list of references used for this task. In addition, the contractor shall also include a list of unused references along with clear justification for not using them. The contractor shall coordinate with the EPA WAM as inclusion or exclusion of any references to the draft document.

2.4 Incorporate EPA comments and additional studies

The EPA WAM will periodically search diverse data bases for potential new information and will provide to the contractor. The contractor shall incorporate any additional studies into revisions to draft report upon receipt from EPA WAM. It is the goal of the EPA WAM to gather as many examples as possible and available to help inform the policy development process. The contractor shall also incorporate EPA WAM's review comments to the document.

2.5 Submit revised report

The contractor shall revise and finalize the health assessment document based upon EPA WAM's review comments.

2.6 Communication piece

The contractor shall provide a brief communication (1- 3 pages) which will aid in briefing EPA managers and senior managers. The communication piece shall be written in plain English language for non-technical people and the relevant scientific studies shall be included as an attachment.

2.7 Response to the Peer Reviewer comments

Upon receipt of the EPA's external expert peer-review of the Contractor's Final Written Report, the EPA WAM will provide the Contractor with the recommended edits and modifications. The Contractor shall address all recommended peer-review modifications. Changes will be documented in a separate report for the record to describe how the peer-review comments were incorporated into the final report.

2.8 Incorporate Peer Reviewer comments to the documents

The contractor shall incorporate all recommended edits and modifications to the documents. The Contractor shall provide the revised final report (and documented changes to the report) to the EPA WAM for review.

2.9 Submit Final Report

Upon the EPA WAM's approval, the Contractor shall send the final revised peer-reviewed report in Microsoft Word, version 2003 or higher, to the EPA WAM

Task 3: Develop Health Assessment document: *Giardia*

3.2 Develop analysis plan and conduct exposure and dose response analysis

Historical technical data that was used to generate the LT2 Rule will be obtained from the EPA's Water Docket.

The health assessment document shall be comprised of a comprehensive review of published literatures on *Giardia* providing all relevant information, the general characteristics of this protozoan, its occurrence in human and animal populations and in water, drinking water exposures, dose response, the health effects associated with *Giardia* infection are important features of the health assessment and all data of this nature should be captured from both US and foreign data bases. The EPA WAM will provide the *Outline for the drinking and ambient water health assessments* to the contractor. The contractor shall also estimate dose based upon 1.2 and 2.0 liters of water/day.

The contractor shall coordinate with the EPA WAM in the collection of datasets for exposure and dose response from various sources for the analysis. Collection of datasets will be conducted such that the Office of Management and Budget (OMB) Information Collection Rule (ICR) will not be triggered.

3.3 Submit draft report of initial findings

The contractor shall prepare a draft *Giardia* health assessment document for EPA WAM's review. The contractor shall insure that all factors that were applied to the health

assessment are stated and are transparent throughout the document. It is EPA's concern that contractor shall include a list of references used for this task. In addition, contractor shall also include a list of unused references along with clear justification for not using them. The contractor shall coordinate with the EPA WAM as inclusion or exclusion of any references to the draft document.

3.4 Incorporate EPA comments and additional studies

The EPA WAM will periodically search diverse data bases for potential new information and will provide to the contractor. The contractor shall incorporate any additional studies into revisions to draft report upon receipt from EPA WAM. It is the goal of the EPA WAM to gather as many examples as possible and available to help inform the policy development process. The contractor shall also incorporate EPA WAM's review comments to the document.

3.5 Submit revised report

The contractor shall revise and finalize the health assessment document based upon EPA WAM's review comments.

3.6 Communication piece

The contractor shall provide a brief communication (1- 3 pages) which will aid in briefing manager and senior managers. The communication piece shall be written in plain English language for non-technical people and the relevant scientific studies shall be included as an attachment.

3.7 Response to the Peer Reviewer comments

Upon receipt of the EPA's external expert peer-review of the Contractor's Final Written Report, the EPA WAM will provide the Contractor with the recommended edits and modifications. The Contractor shall address all recommended peer-review modifications. Changes will be documented in a separate report for the record to describe how the peer-review comments were incorporated into the final report.

3.8 Incorporate Peer Reviewer comments to the documents

The contractor shall incorporate all recommended edits and modifications to the documents. The Contractor shall provide the revised final report (and documented changes to the report) to the EPA WAM for review.

3.9 Submit Final Report

Upon the EPA WAM's approval, the Contractor shall send the final revised peer-reviewed report in Microsoft Word, version 2003 or higher, to the EPA WAM

Period of Performance/Milestones: It is the Contractor's responsibility to coordinate with EPA WAM while conducting these tasks.

| Task | Milestone | Date due |
|------|---|--|
| 1 | 1.1 Work Plan | Within 15 calendar days of receipt of WA |
| 1 | Kick-off meeting with EPA WAM | 1 week after WP approval |
| 2 | 2.2 Develop analysis plan and conduct exposure and dose response analysis | 3 Weeks after WP approval |
| 2 | 2.3 Submit draft report of initial findings | 1 month after WP approval |
| 2 | 2.4 Incorporate EPA comments and additional studies, if identified | 6 weeks after WP approval |
| 2 | 2.5 Submit revised report | 2 months after WP approval |
| 2 | 2.6 Communication Piece | TBD |
| 2 | 2.7 Response to the Peer Reviewer comments | TBD |
| 2 | 2.8 Incorporate Peer Reviewer comments | TBD |
| 2 | 2.9 Submit final report | TBD |
| 3 | 3.2 Develop analysis plan and conduct exposure and dose response analysis | 3 Weeks after WP approval |
| 3 | 3.3 Submit draft report of initial findings | 1 month after WP approval |
| 3 | 3.4 Incorporate EPA comments and additional studies, if identified | 6 weeks after WP approval |
| 3 | 3.5 Submit revised report | 2 months after WP approval |
| 3 | 3.6 Communication Piece | TBD |
| 3 | 3.7 Response to the Peer Reviewer comments | TBD |
| 3 | 3.8 Incorporate Peer Reviewer comments | TBD |
| 3 | 3.9 Submit final report | TBD |

Knowledge and Skills Required: The Contractor shall have expertise in preparing the aforementioned materials and be knowledgeable with the various fields of discipline discussed in this PWS. The contractor shall be an accomplished microbial risk assessor with experience in environmental media, especially water. The contractor shall have knowledge and experience with the *Cryptosporidium* and *Giardia spp.* protozoa in water and water/wastewater treatment/disinfection effectiveness. The contractor shall be experienced in evaluation of data bases, statistics, and modeling regarding human exposure, dose response and health effects for application in microbial risk assessments.

General Requirements of the Work Assignment and Schedule:

Due Dates: The Contractor shall provide due dates that are mutually acceptable with the EPA WAM. The Contractor shall notify the EPA WAM in advance, if a due date will not be met and request a revised date.

Delays: The Contractor shall make every effort to ensure there are no Contractor-caused delays. If a delay is inevitable, it is the Contractor's responsibility to notify the EPA WAM at the first sign of said delay. A revised schedule will then be worked out.

Draft Documents: The Contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. EPA WAM will provide comments on draft submissions prior to submission of final documents.

Final Documents: The Contractor shall submit final documents both electronically and in hardcopy to EPA WAM.

Final Documents: The Contractor shall revise and incorporate all EPA's comments and submit final documents both electronically and in hardcopy (Microsoft version 2003 or higher) to EPA WAM. The Agency may decide to publish the report on the web. If this occurs, the report will need to be 508 compliant and the COR will provide appropriate technical direction.

Final Peer Reviewed Document: Upon receipt of the EPA's external expert peer-review of the Contractor's Final Written Report, the EPA WAM will provide the Contractor with the recommended edits and modifications. The Contractor shall address all recommended peer-review modifications. Changes will be documented in a separate report for the record to describe how the peer-review comments were incorporated into the final report. The Contractor shall provide the revised final report (and documented changes to the report) to the EPA WAM for review. Upon the EPA WAM's approval, the Contractor shall send the final revised peer-reviewed report in Microsoft Word, version 2003 or higher, to the EPA WAM.

MEETINGS, CONFERENCES, TRAINING EVENTS, AWARD CEREMONIES AND RECEPTIONS:

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA PO as needed and provided to the Contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the EPA PO.

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| EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment | | Work Assignment Number 2-09 | | | | | | | | |
| | | <input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000001 | | | | | | | | |
| Contract Number EP-C-11-005 | Contract Period 01/01/2011 To 12/31/2013 Base Option Period Number 2 | Title of Work Assignment/SF Site Name Human Health Assessment..... | | | | | | | | |
| Contractor ICF INCORPORATED, L.L.C. | | Specify Section and paragraph of Contract SOW See PWS | | | | | | | | |
| Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval | | Period of Performance From 01/01/2013 To 12/31/2013 | | | | | | | | |
| Comments: | | | | | | | | | | |
| <input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund | | | | | | | | | | |
| SFO (Max 2) <input type="checkbox"/> Note: To report additional accounting and appropriations data use EPA Form 1900-69A. | | | | | | | | | | |
| Line | DCN (Max 6) | Budget/FY (Max 4) | Appropriation Code (Max 6) | Budget Org/Code (Max 7) | Program Element (Max 9) | Object Class (Max 4) | Amount (Dollars) | (Cents) | Site/Project (Max 8) | Cost Org/Code (Max 7) |
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| Total: | | | | | | | | | | |
| Work Plan / Cost Estimate Approvals | | | | | | | | | | |
| Contractor WP Dated: | | Cost/Fee: | | | | LOE: | | | | |
| Cumulative Approved: | | Cost/Fee: | | | | LOE: | | | | |
| Work Assignment Manager Name Shamima Akhter | | | | | | Branch/Mail Code: | | | | |
| _____ (Signature) (Date) | | | | | | Phone Number 202-566-0000 | | | | |
| | | | | | | FAX Number: | | | | |
| Project Officer Name Shirley Harrison | | | | | | Branch/Mail Code: | | | | |
| _____ (Signature) (Date) | | | | | | Phone Number: 202-566-1107 | | | | |
| | | | | | | FAX Number: | | | | |
| Other Agency Official Name Shirley Harrison | | | | | | Branch/Mail Code: | | | | |
| _____ (Signature) (Date) | | | | | | Phone Number: 202-566-1107 | | | | |
| | | | | | | FAX Number: | | | | |
| Contracting Official Name Sandra Stargardt-Licis | | | | | | Branch/Mail Code: | | | | |
| _____ (Signature) (Date) | | | | | | Phone Number: 513-487-2006 | | | | |
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**PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-11-005
WORK ASSIGNMENT # 2-09 Amendment 1**

Title: Human Health Assessment: *Cryptosporidium* and *Giardia* in drinking and ambient water

Work Assignment Manager: Shamima Akhter (Mail Code 4304T)
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Washington, DC 20460
Phone (202) 566-1341
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Alternate WAM: John Ravenscroft (Mail Code 4304T)
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E-mail: ravenscroft.john@epa.gov

Period of Performance: January 1, 2013 through December 31, 2013

Contractor SOW: 2.2, 3.1.6, and 3.1.8

Purpose of Amendment:

The purpose of this amendment is to provide additional LOE to: 1) complete the remaining tasks under Task 2 (2.6 thru 2.9) and Task 3 (3.6 thru 3.9) which was not funded in the original work assignment; 2) add new sections to the outline under Task 2.2 and 3.2; and 3) the preparation of the draft reports for external peer review, and their related activities. This includes addressing EPA internal management review comments.

The contractor shall add a new section 'Screening Level Risk Assessment' under Task 2.2 and 3.2. The new section will be added in the *Outline for Drinking Water and Ambient Water Health Assessments*. The outline has already been provided to the contractor by the EPA WAM under the original work assignment. EPA believes that users will benefit for conducting risk assessment for these important pathogens. The Deliverables under Task 2 and 3 have necessitated additional rounds of review and editing by the EPA WAM and EPA Management that were not anticipated when the original work assignment was prepared.

The quality assurance and monthly progress reports, still apply to this amendment. The Contractor shall provide a cost estimate in response to this amendment for all of the remaining tasks.

Deliverables for task 2:

- Two (2) more drafts to get to peer review version (includes chapter 5 new outline with screening level RA)
- Two (2) drafts of response to comment
- Three (3) drafts (1 major and 2 minor) post peer review drafts

Deliverables for task 3:

- Two (2) more drafts to get to peer review version (includes chapter 5 new outline with screening level RA)
- Two (2) drafts of response to comment
- Three (3) drafts (1 major and 2 minor) post peer review drafts

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| EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment | | | | | | Work Assignment Number 2-10 | | | | |
| | | | | | | <input type="checkbox"/> Other <input type="checkbox"/> Amendment Number: | | | | |
| Contract Number EP-C-11-005 | | | Contract Period 01/01/2011 To 12/31/2013 Base Option Period Number 2 | | | Title of Work Assignment/SF Site Name Secondary Contact | | | | |
| Contractor ICF INCORPORATED, L.L.C. | | | | Specify Section and paragraph of Contract SOW 3.1, 3.3, and 3.4 | | | | | | |
| Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval | | | | | | Period of Performance From 01/01/2013 To 12/31/2013 | | | | |
| Comments: | | | | | | | | | | |
| <div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund <div style="flex-grow: 1; text-align: center;">Accounting and Appropriations Data</div> <input checked="" type="checkbox"/> Non-Superfund </div> | | | | | | | | | | |
| <div style="display: flex; justify-content: space-between;"> <div> SFO (Max 2) <input type="checkbox"/> </div> <div> Note: To report additional accounting and appropriations data use EPA Form 1900-69A. </div> </div> | | | | | | | | | | |
| Line | DCN (Max 6) | Budget/FY (Max 4) | Appropriation Code (Max 6) | Budget Org/Code (Max 7) | Program Element (Max 9) | Object Class (Max 4) | Amount (Dollars) | (Cents) | Site/Project (Max 8) | Cost Org/Code (Max 7) |
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| Authorized Work Assignment Ceiling | | | | | | | | | | |
| Contract Period: Cost/Fee: LOE: 01/01/2011 To 12/31/2013 | | | | | | | | | | |
| This Action: | | | | | | | | | | |
| Total: | | | | | | | | | | |
| Work Plan / Cost Estimate Approvals | | | | | | | | | | |
| Contractor W/P Dated: Cost/Fee: LOE: | | | | | | | | | | |
| Cumulative Approved: Cost/Fee: LOE: | | | | | | | | | | |
| Work Assignment Manager Name Gary Russo <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between; margin-top: 5px;"> <div>(Signature)</div> <div>(Date)</div> </div> | | | | | | | Branch/Mail Code: Phone Number 202-566-1335 FAX Number: | | | |
| Project Officer Name Shirley Harrison <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between; margin-top: 5px;"> <div>(Signature)</div> <div>(Date)</div> </div> | | | | | | | Branch/Mail Code: Phone Number: 202-566-1107 FAX Number: | | | |
| Other Agency Official Name Shirley Harrison <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between; margin-top: 5px;"> <div>(Signature)</div> <div>(Date)</div> </div> | | | | | | | Branch/Mail Code: Phone Number: 202-566-1107 FAX Number: | | | |
| Contracting Official Name Sandra Stargardt-Licis <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between; margin-top: 5px;"> <div>(Signature)</div> <div>(Date)</div> </div> | | | | | | | Branch/Mail Code: Phone Number: 513-487-2006 FAX Number: | | | |

**PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-11-005
WORK ASSIGNMENT #2-10**

Title: Secondary Contact Water Quality Standards for Pathogens

Work Assignment Manager: Gary Russo (Mail Code 4305T)
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Alternate WAM: Sharon Nappier (Mail Code 4304T)
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E-mail: nappier.sharon@epa.gov

Period of Performance: January 1, 2013 through December 31, 2013

Contractor SOW: 3.1, 3.3, and 3.4

CBI: No confidential business information will be needed for this work assignment.

Background:

An effort is currently underway to revise EPA's bacteriological water quality criteria under section 304(a) of the Clean Water Act (CWA). Both the current and proposed revised criteria primarily address water quality standards for "primary contact" recreational uses and do not significantly address "secondary contact" recreational uses. Primary contact recreation is typically defined as water-based recreational activities that could be expected to result in the ingestion of or immersion in water such as swimming, water skiing, or surfing. Secondary contact recreation is typically defined as water-based recreational activities where contact with the water is either incidental or accidental, and the probability of ingesting appreciable quantities of water is minimal.

Current EPA policy allows States, tribes and territories to adopt bacteriological criteria for secondary contact uses that are less stringent than criteria for primary contact uses.

The justification for less stringent secondary contact criteria is based on the assumption that secondary contact activities are associated with exposure to fewer pathogenic organisms. It is believed that a higher concentration of pathogens in water is counterbalanced by a lower potential exposure to those pathogens, resulting in the same risk of illness in secondary recreational activities as risks associated with primary recreational activities. However, the potential for pathogen exposure during different recreational activities is not well characterized, and there is currently no scientific consensus on whether or not they are in fact associated with different risks of illness (differential risk).

Although there is a body of scientific literature addressing the risk of illness associated with various water-based recreational activities, the relationships between different activities, water quality, and health risks are not well understood. The wide ranges of existing studies often have ambiguous results or support conflicting conclusions. Such ambiguity and/or disagreement may be due to a variety of reasons, including differences in the questions being addressed, differences, biases and/or flaws in the way the studies were designed or conducted, differences in interpretation of the study results, or simply due to chance.

The purpose of this Performance Work Statement (PWS) is to examine the evidence for or against differential risk by conducting a systematic review. A systematic review is a specific type of literature review that focuses on a specific research question and tries to identify, appraise, select and synthesize all high quality research and evidence relevant to that question. The overall goal of a systematic review is to provide an objective and transparent synthesis of research results that minimizes bias. The systematic review from this PWS will provide an up-to-date, state-of-the-art evaluation of the current scientific knowledge of the health risks associated with different water-based recreational activities in water contaminated by fecal material. The results and conclusions of the systematic review will be used to inform EPA policies and decisions associated with recreational water quality standards for the protection of public health.

Performance Work Statement (PWS):

The scope of work in this PWS will fall under the following tasks:

Task 1 –Work plan, quality assurance, and monthly progress reports

Task Area 1.2. Work plan

The contractor shall develop a work plan to address all tasks in the performance work statement (PWS). The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If one or more

subcontractor(s) are proposed and they are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. The number and professional level of hours charged and total dollars for each task will be provided. Other costs greater than \$100.00 shall be itemized.

- Deliverable – Work plan.
- Deadline – fifteen (15) calendar days after receipt of work assignment

Task Area 1.3. Quality assurance

Upon completion of the systematic review, the contractor shall complete the EPA Office of Water Information Quality Guidelines checklist and supporting narrative. See Attachment 2.

- Deliverable – Completed Information Quality Guidelines checklist
- Deadline – seven (7) calendar days following completion of the systematic review.

Task Area 1.4. Monthly Progress Reports

The contractor shall provide progress and financial reports to the EPA WAM each month. The contractor shall also provide any information related to the execution of this PWS when ever requested by the EPA WAM. The progress report shall indicate, in a separate QA/QC section, whether QA/QC issues have been identified and how they will be resolved. If significant QA/QC issues are encountered, the contractor shall contact the EPA WAM immediately to discuss the issue. If work ceases because of QA/QC issues, the contractor shall not resume work until receiving written approval from the EPA WAM. Monthly financial reports shall at minimum include a table with the invoice LOE and costs for each task and task area in this PWS.

Task 2 – Develop a systematic review of the scientific evidence related to differential risk of illness with different water-based recreational activities.

Task Area 2.2. Develop a systematic review protocol.

The contractor shall develop a systematic review protocol that reflects current state-of-the-art methods and procedures for conducting systematic reviews, and reflects the general plan outlined in the systematic review Methods Report developed in Task Area 2.1 under the previous work assignment # 1-10. If, after beginning work on the review protocol itself, the contractor believes the review protocol may need to deviate from the planned methods, procedures, or approaches outlined in the Methods Report, the contractor shall identify those methods, procedures, or approaches, describe how and why the protocol should deviate from them, and identify how such a deviation may potentially

impact the goals and objectives of the systematic review.

The review protocol shall be developed in close collaboration with the EPA WAM and other EPA staff designated by the EPA WAM. The contractor shall not begin the review itself until the review protocol has been fully developed and approved by the EPA WAM. At a minimum, the review protocol shall address the following key areas:

Scientific questions to be addressed. The review protocol shall clearly describe the scientific question(s) to be addressed by the review, and how the answers to those questions may provide meaningful information to inform EPA decision-making about primary versus secondary contact criteria and designated uses. The review questions shall be developed in close consultation with the EPA WAM, and be stated clearly and precisely in the review protocol. Once the final scientific questions are determined, the sole purpose of the systematic review shall be to address only those questions. Under no circumstances shall the systematic review deviate from addressing the established scientific questions without written approval from the EPA WAM.

Background. The review protocol shall have a background section that clearly communicates the key contextual factors and conceptual issues relevant to the review questions. It should explain why the review is required and provide the rationale underpinning the inclusion criteria and the focus of the review questions.

Search strategy. The review protocol shall specify the search strategy that will be used to identify relevant studies that could potentially be included in the review. The contractor shall clearly and transparently describe all steps in the search strategy so that the search results can be reliably reproduced. These details include, but are not limited to, specifying the databases and additional sources that will be searched and the search terms to be used. Provisions for repeating the searches during the review process and details about how the contractor will manage references shall also be specified.

Inclusion criteria. The review protocol shall describe the criteria for selecting studies that will be included in the review. Factors to consider include population, interventions, comparators, outcomes, and study design. To avoid publication bias, the inclusion criteria shall consider all relevant studies regardless of publication status, including but not limited to peer-reviewed journals, reports, book chapters, conference abstracts, theses, informal reports, and unpublished studies. Studies in any language shall be considered to avoid language bias. If translation of all relevant studies is not feasible, the inclusion criteria shall describe how non-English studies will be addressed in the review.

Study selection. The contractor shall specify in the review protocol the process by which decisions on the selection of studies will be made. Study selection is usually conducted in two stages: an initial screening of titles and abstracts against the inclusion criteria to identify potentially relevant papers, followed by complete screening of papers identified

as possibly relevant in the initial screening. The review protocol shall clearly and fully describe the processes that will be used for both stages of study selection. The contractor shall also specify the number of researchers who will screen titles and abstracts and then full papers, and the method for resolving disagreements about study eligibility.

Data abstraction. To the extent possible, the review protocol shall describe the information that will be extracted from studies identified for inclusion in the review. The review protocol shall clearly state the procedures expected to be used for data extraction, including the number of researchers who will extract the data and how discrepancies will be resolved. The protocol shall also specify whether authors of primary studies will be contacted to provide missing or additional data. If non-English language papers are to be included, translation arrangements will also be specified.

Quality assessment. The protocol shall provide details of the method of study appraisal to be used, including examples of the specific quality criteria. The review protocol shall specify the process for appraising study quality, and the process for weighting studies on the basis of their appraised quality. The review protocol shall also specify how disagreements among study appraisers will be resolved.

Data Synthesis. To the extent possible, the protocol shall specify the strategy for data synthesis. The protocol shall describe the conditions necessary to perform a meta-analysis and how the meta-analysis will be conducted. To the extent possible, the protocol shall describe how heterogeneity will be explored and quantified, and whether a fixed or random-effects model or both will be used and why. The protocol shall also specify the outcomes of interest and what effect measures will be used. The protocol shall describe any planned subgroup or sensitivity analyses or investigation of publication bias and the reasons why. An approach to conducting narrative synthesis shall also be developed and described. If any of the above analyses are not planned, justification for not performing them shall be provided.

QA/QC. The contractor shall incorporate into the review protocol all QA/QC procedures that will be followed while conducting the systematic review. These QA/QC procedures shall be specified within the relevant areas of the review protocol so that the QA/QC procedures to be followed are readily apparent during performance of each stage of the systematic review process.

- Deliverable – Systematic review protocol.
- Deadline – sixty (60) days after the EPA WAM approves the Methods Report. The WAM will provide the contractor with technical direction via written instructions to begin work on the review protocol.

Task Area 2.3. Revise the review protocol in response to possible peer review comments.

After the systematic review protocol has been approved by the EPA WAM, the EPA WAM may decide that a peer review of the protocol by independent experts outside the EPA is needed. Should the EPA WAM decide that an external peer review is necessary, the contractor shall provide assistance and advice in developing the charge for the peer review and in interpreting the peer review comments. Should the EPA WAM decide that the review protocol needs to be revised in response to an external peer review, the contractor shall revise the review protocol in accordance with the technical direction provided by the EPA WAM. The contractor shall adhere to the same standards of quality as when initially developing the review protocol as specified in Task Area 2.2. Revisions shall be performed in close collaboration with the EPA WAM and other EPA staff designated by the EPA WAM. The contractor shall not begin the review itself until the review protocol has been finalized and the contractor receives written instructions to do so by the EPA WAM.

- Deliverable – Revised review protocol.
- Deadline – thirty (30) days after receiving peer review comments.

Task Area 2.4. Conduct the systematic review.

Upon completion of the final review protocol and receiving written instructions by the EPA WAM, the contractor shall conduct the systematic review as specified in the review protocol. During the screening phase, the contractor shall inform the EPA WAM of the results of initial screening process before beginning full screening of potentially relevant papers. When performing the systematic review, the contractor shall strictly adhere to the review protocol and shall not deviate from it without explicit written permission from the EPA WAM.

Although one objective of the systematic review is to strictly adhere to the review protocol once finalized, modification of the finalized review protocol may be appropriate in some circumstances such as when a clearer understanding of the review question(s) becomes apparent, or when initial screening of papers using the specified eligibility criteria results in too few or too many papers. If, after initial consideration of the studies being reviewed, it becomes apparent that a change in direction may be required, the contractor shall immediately cease review activities and notify the EPA WAM. If the EPA WAM determines that protocol modifications are needed, the contractor shall modify the protocol in consultation with the EPA WAM. The contractor shall not resume review activities until the final modified review protocol is reviewed and approved by the EPA WAM and the contractor receives written instructions to resume review activities. Protocol modifications shall be clearly and fully documented in a protocol addendum and in the final report of the review findings. This documentation shall include a clear

description of the differences between the initial and amended protocol, and the implications of the modification on the review findings. **Under no circumstances shall the protocol be modified or the review altered because of awareness of the results of individual studies.**

Throughout the review process, the contractor shall provide progress reports to the EPA WAM. The contractor shall also provide electronic copies of all documents that were screened during the study selection process or used in the systematic review. A database of complete document citations along with the file name of the electronic copy shall also be provided to the EPA WAM as an Endnote database or another electronic format that can easily be imported into Endnote.

At the conclusion of the systematic review, the contractor shall provide a brief report outlining the results of the review. The report shall be well written, organized thoughtfully, concise, grammatically correct, have no spelling errors, academically rigorous, contain high quality tables and figures if needed, and formatted so that it can serve as the foundation for developing a manuscript to be submitted for publication in a high-quality peer-reviewed journal.

- Deliverable – Report on review results.
- Deadline – ninety (90) days after receiving instructions from the EPA WAM to begin the systematic review.

Task Area 2.5. Develop one or more manuscripts for publication of the systematic review.

At the conclusion of the systematic review, the contractor shall develop one or more manuscripts for publication of the systematic review. The manuscript(s) shall be developed in close consultation with the EPA WAM with the goal of publishing the systematic review in a high quality, high impact, peer-reviewed journal. The manuscript(s) shall be organized thoughtfully, written concisely, grammatically correct, academically rigorous, contain high quality tables and figures when appropriate, and formatted for the journal being targeted. The manuscript(s) shall be developed in a way that allows reformatting for submission to other journals if the need arises. The contractor shall revise the manuscript(s) as instructed via technical direction by the EPA WAM in response to reviewer comments, and develop written responses to reviewer comments for submission to the journal editor. The contractor shall conform to the same standards of quality when revising the manuscript(s) as specified above for initially developing the manuscript(s). The contractor shall also prepare the Information Quality Guidelines Checklist necessary for products that EPA disseminates to the public under EPA's Information Quality Guidelines.

- Deliverable – Draft manuscript.
- Deadline – thirty (30) days after conclusion of the systematic review.

Task Area 3 - General Project Support

Task Area 3.1. Prepare briefing materials and other supporting documents pertaining to the systematic review.

Briefing materials and other supporting documents will be needed during the systematic review development process and after the review is published. The contractor shall aid in the development of any materials or presentations for these purposes. This may include but is not limited to preparing interim project updates and other materials for internal and external audiences as requested by the EPA WAM, briefing documents, PowerPoint presentations, and other supporting documents as needed. The contractor may be requested by the EPA WAM to participate in and/or conduct briefings or participate in seminars or talks related to the systematic review.

- Deliverable – Requested materials and supporting documents.
- Deadline – As agreed upon by the EPA WAM and contractor

Task Area 3.2. Support options development and analyses for potential changes to EPA policies related to bacteriological water quality standards.

As the results and conclusions of the systematic review become clear, the EPA may want to consider alternative policies related to bacteriological water quality standards. The contractor shall aid in the development of potential alternative policy options. These activities may include, but are not limited to, performing additional research and analysis of existing scientific data and information, analysis of the potential public health outcomes resulting from policy modifications, and the analysis of water quality standard implementation implications associated with the adoption of alternative bacteriological water quality standards. The contractor may be requested to participate in and/or conduct briefings or other presentations related to this work.

- Deliverable – Requested materials.
- Deadline – As agreed upon by the EPA WAM and contractor

Travel:

Travel may be needed as deemed necessary by the EPA WAM. No contractor travel outside of the Washington, D.C. metro area is required.

Conferences:

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA WAM as needed and provided to the Contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the EPA WAM.

Knowledge and Skills Required:

The contractor shall have the necessary scientific knowledge and expertise to develop the aforementioned materials in this PWS that are high quality and use state-of-the-art methods. Specifically, the contractor shall have experience designing, performing, and publishing primary scientific research evaluating the health effects of environmental pollution, as well as experience designing, performing, and publishing systematic- and meta-analyses of such studies. The contractor shall have expertise in epidemiological studies that evaluate microbiological water pollution using fecal indicator organisms. The contractor shall be proficient in advanced state-of-the-art statistical methods typically used to analyze epidemiological studies and perform meta-analyses. The contractor should also be competent in analytical methods used to monitor microbial water pollution (including molecular techniques), the determination of human exposure to environmental contaminant sources, and disease endpoints related to microbial exposure through contact with water.

General Requirements of the Work Assignment and Schedule:Due Dates

The contractor shall mutually acceptable due dates with EPA WAM. The contractor shall notify the EPA WAM in advance, if a due date will not be met and negotiate a mutually acceptable revised due date.

Delays

The contractor shall provide sufficient qualified man-power to ensure there are no avoidable delays. If a delay outside the control of the contractor is unavoidable, the contractor shall immediately notify the EPA WAM and negotiate a mutually acceptable revised schedule.

Draft Documents

The contractor shall submit draft or interim work products requested by the EPA WAM. Draft or interim work products shall be prepared in an electronic format compatible with

Microsoft Office 2007 or Endnote X. The EPA WAM will provide the contractor with comments on draft work products in electronic format. Work products shall be deemed draft until designated as final by the EPA WAM.

Final Documents

The contractor shall submit final documents electronically to the EPA WAM.

**MEETINGS, CONFERENCES, TRAINING EVENTS, AWARD CEREMONIES
AND RECEPTIONS:**

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA PO as needed and provided to the Contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the EPA PO.

ATTACHMENT 1

QAPP Requirement for Projects Using Secondary Data

A project involving secondary data gathers and uses existing data for purposes other than those for which they may have been originally collected. These secondary data may be obtained from many sources including literature, industry, computerized databases and information systems, and computerized or mathematical models of environmental processes. For projects that use secondary data, a QAPP shall be prepared that include the requirements identified below. If primary data will also be generated as part of the project, then the information below can be incorporated into the associated QAPP to address the secondary data. The following requirements should be addressed as applicable.

Section 1. Project Objectives, Organization, and Responsibilities

- 1.1 The purpose of study shall be clearly stated.
- 1.2 Project objectives shall be clearly stated.
- 1.3 The secondary data needed to satisfy the project objectives shall be identified. Requirements relating to the type of data, the age of data, geographical representation, temporal representation, and technological representation, as applicable, shall be specified.
- 1.4 The planned approach for evaluating project objectives, including formulas, units, definitions of terms, and statistical or other types of data analysis. Assumptions and or recommendations based on the data analysis shall also be included if applicable.
- 1.5 Responsibilities of all project participants shall be identified, meaning that key personnel and their organizations shall be identified, along with the designation of responsibilities for planning, coordination, data gathering, data analysis, report preparation, and quality assurance, as applicable.

Section 2. Sources of Secondary Data

- 2.1 The source(s) of the secondary data must be specified.
- 2.2 The rationale for selecting the source(s) identified shall be discussed.
- 2.3 The sources of the secondary data will be identified in any project deliverable.

Section 3. Quality of Secondary Data

- 3.1 Quality requirements of the secondary data must be specified. These requirements must be appropriate for their intended use. Accuracy, precision, representativeness, completeness, and comparability need to be addressed, if

applicable. (If appropriate, a related QAPP containing this information can be referenced.)

- 3.2 The procedures for determining the quality of the secondary data shall be described.
- 3.3 If no quality requirements exist, this shall be stated in the QAPP. If no quality requirements exist or if the quality of the secondary data will not be evaluated by EPA, the QAPP shall require that a disclaimer be added to any project deliverable to indicate that the quality of the secondary data has not been evaluated by EPA for this specific application. The wording for the disclaimer shall be defined.

Section 4. Data Reporting, Data Reduction, and Data Validation

- 4.1 Data reduction procedures specific to the project shall be described, including calculations and equations.
- 4.2 The data validation procedures used to ensure the reporting of accurate project data shall be described.
- 4.3 The expected product document that will be prepared shall be specified (*e.g.*, journal article, final report, *etc.*).

ATTACHMENT 2

Office of Water

Information Quality Guidelines:

Pre-Dissemination Review Guidance and Checklists

version 2.2 (January 10, 2003)

BACKGROUND

In order to comply with Section 515 of the Treasury and General Government Appropriations Act for FY 2002 (Public Law 106-554), the Office of Management and Budget developed guidelines that "provide policy and procedural guidance for ensuring and maximizing the quality, objectivity, utility, and integrity of information, including statistical information, disseminated by Federal agencies."

In response to OMB's guidelines (FRL-7157-8, March 2002), EPA developed the *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* (The Guidelines), which contains EPA's policy and procedural guidance for ensuring and maximizing the quality of the information we disseminate. "Quality" refers to objectivity, integrity, and utility.

The Guidelines also:

- outline administrative mechanisms for EPA pre-dissemination review of information products
- enable affected persons to file complaints regarding disseminated information that they believe to be noncompliant with EPA's Guidelines.

Implementation began *October 1, 2002*.

For more information, visit <http://www.epa.gov/oei/qualityguidelines/>

In order to ensure that information meets The Guidelines, the following guidance and checklists should be used prior to dissemination.

OVERVIEW

- What information is covered under The Guidelines?

version 2.2 (January 10, 2003)

- Is your organization in compliance with EPA's existing Quality System and Office of Water's Quality Management Plan?
- What type of information do I have?
- Do additional guidelines apply for externally gathered data?
- Checklists for Pre-Dissemination Review
- What are Requests for Correction and Requests for Reconsideration, and how does OW respond to them?

WHAT INFORMATION IS COVERED UNDER THE GUIDELINES?

These guidelines apply only to *information* EPA disseminates to the public.

What DO The Guidelines cover?

- EPA prepares the information and distributes it to support or represent EPA's viewpoint, or to formulate or support a regulation, guidance, or other Agency decision or position.
- EPA distributes information prepared or submitted by an outside party in a manner that reasonably suggests that EPA endorses or agrees with it.
- EPA reviews and comments on information distributed by an outside party in a manner that indicates EPA is endorsing it, directs the outside party to disseminate it on EPA's behalf, or otherwise adopts or endorses it.

What DON'T The Guidelines cover?

- Distribution of information for government employees
- EPA response to FOIA, FACA, or similar legislation
- Correspondence directed to individuals or persons
- Information presented solely to Congress
- Ephemeral information (press releases, fact sheets, press conferences)
- Background information (published articles distributed by libraries, or other non-EPA endorsed distributions)
- Information distributed by recipients of EPA grants, contracts, or cooperative agreements *unless* EPA adopts or endorses the information
- Information in public filings, including information submitted to EPA, either voluntarily or under mandates/requirements
- Distribution of information in judicial cases or administrative adjudication

IS YOUR ORGANIZATION IN COMPLIANCE WITH EPA'S EXISTING QUALITY SYSTEM AND OFFICE OF WATER'S QUALITY MANAGEMENT PLAN?

Many of EPA's current quality assurance practices fulfill much of EPA's Information Quality Guidelines. Examples of these policies are: Quality System, Peer Review, Action Development

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|---|---|---|-------------------------------|----------------------------|----------------------------|-------------------------------|------------------|---------|-------------------------|--------------------------|
| EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment | | Work Assignment Number 2-11 | | | | | | | | |
| | | <input type="checkbox"/> Other <input type="checkbox"/> Amendment Number: | | | | | | | | |
| Contract Number EP-C-11-005 | Contract Period 01/01/2011 To 12/31/2013 Base Option Period Number 2 | Title of Work Assignment/SF Site Name TSM for Alt Hlth Relationships | | | | | | | | |
| Contractor ICF INCORPORATED, L.L.C. | | Specify Section and paragraph of Contract SOW 3.1, 3.3, 3.6 | | | | | | | | |
| Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval | | Period of Performance From 01/01/2013 To 12/31/2013 | | | | | | | | |
| Comments: | | | | | | | | | | |
| <input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund | | | | | | | | | | |
| SFO (Max 2) <input type="checkbox"/> Note: To report additional accounting and appropriations data use EPA Form 1900-69A. | | | | | | | | | | |
| Line | DCN (Max 6) | Budget/FY (Max 4) | Appropriation Code (Max 6) | Budget Org/Code (Max 7) | Program Element (Max 9) | Object Class (Max 4) | Amount (Dollars) | (Cents) | Site/Project (Max 8) | Cost Org/Code (Max 7) |
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| Total: | | | | | | | | | | |
| Work Plan / Cost Estimate Approvals | | | | | | | | | | |
| Contractor WP Dated: | | | | Cost/Fee: | | LOE: | | | | |
| Cumulative Approved: | | | | Cost/Fee: | | LOE: | | | | |
| Work Assignment Manager Name John Ravenscroft | | | | | | Branch/Mail Code: | | | | |
| _____ (Signature) | | | | | | _____ (Date) | | | | |
| Project Officer Name Shirley Harrison | | | | | | Phone Number 202-566-1101 | | | | |
| _____ (Signature) | | | | | | _____ (Date) | | | | |
| Other Agency Official Name | | | | | | FAX Number: | | | | |
| _____ (Signature) | | | | | | _____ (Date) | | | | |
| Contracting Official Name Sandra Stargardt-Licis | | | | | | Branch/Mail Code: | | | | |
| _____ (Signature) | | | | | | _____ (Date) | | | | |
| | | | | | | Phone Number: 513-487-2006 | | | | |
| | | | | | | FAX Number: | | | | |

PERFORMANCE WORK STATEMENT
ICF CONTRACT # EP-C-11-005
WORK ASSIGNMENT #2-11

Title: Support for Developing Technical Support Materials for Deriving Site-Specific Water Quality Criteria Based on Alternative Health Relationships

Work Assignment Manager: John Ravenscroft (Mail Code 4304T)
Office of Water, Office of Science and Technology
Health and Ecological Criteria Division
1200 Pennsylvania Ave, N.W.
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Alternate WAM: Shamima Akhter (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Avenue, NW
Washington DC, 20460
Phone: 202-566-1341
E-mail: akhter.shamima@epa.gov

Period of Performance: January 1, 2013 through December 31, 2013

Contract PWS: 3.1, 3.3, 3.6

****Note:** No CBI data will be needed in the course of this work assignment.

Goal: The overall goal of this work assignment is to develop implementation guidance for States and Tribes to use in developing site-specific water quality criteria based on alternative human health associations with water quality measures.

Objectives:

1. Produce a comprehensive report for internal EPA evaluation detailing the framework, process, and scientific foundation that the intended end users of this information (i.e., States, Tribes, and EPA) can utilize in developing and evaluating a site-specific water quality standards package based on an alternative human health relationship with water quality.
2. Respond to EPA and peer review comments on the report covered in Objective 1.
3. Produce a polished report in response to Objective 2 that the Agency can publish on its website
4. Produce communications materials to accompany reports including: a 1 to 2 page nontechnical synopsis, a technical summary document written in non-academic style for a non-scientific audience, a 'questions and answers' (Q&As) document covering areas of potential inquiry from nontechnical and technical audiences (both internal and external), and others as determined by the EPA WAM via technical direction.

Background: EPA recently issued new CWA 304(a) Recreational Water Quality Criteria (RWQC) in November 2012. The science underpinning the new criteria describes human health effects and water quality studies conducted in waters impacted primarily by human sources of fecal contamination. EPA recommended water quality criteria for fecal indicator bacteria based on the epidemiological studies conducted by EPA's Office of Research and Development (ORD). These studies were conducted at a subset of recreational waters impacted by human fecal contamination. While EPA considers these recommended criteria to be scientifically defensible and protective of the use on a national basis, the Agency recognized that certain site-specific conditions exist that would allow alternative, equally protective, criteria to be considered for Water Quality Standards. EPA clarified additional potential approaches to developing site-specific water quality criteria in Section 5 of the draft RWQC published in December 2011. These approaches focused on three main areas: 1) alternative indicators; 2) alternative sources of fecal contamination; and 3) alternative health relationships. This work assignment addresses the alternative health relationship approach.

Generally speaking, the alternative health relationship approach would consist of the development of a site-specific recreational water quality criteria derived from a human health association with water quality that differs from the one EPA has used as the basis for the nationally-applicable 2012 recommendations. EPA has committed to publishing implementation guidance, hereafter termed Technical Support Materials (TSM), for use by States and Tribes who may be interested in pursuing the development of site-specific criteria. This work assignment covers the various aspects needed to develop these TSM, including the collation and development of background and supplemental information needed for the

application of this approach in the development of site-specific Water Quality Standards packages to be evaluated by EPA.

Quality Assurance: The tasks in this work assignment (WA) require the use of secondary data/analyses and fall under the scope of the approved contract-level QAPP. Consistent with the Agency's quality assurance (QA) requirements, the contractor must assure the quality and analyses of the secondary data and other data collected to be used under this work assignment.

The Contractor shall discuss with the EPA WAM if any of the specific work assignment tasks are not readily covered under the approved QAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a WA-specific QAPP supplement, which must be approved by the EPA before activities covered by the additional QA language begin under this work assignment.

Task 1: Work plan, monthly progress reports and quality assurance

Task 1.1: Work plan

The contractor shall develop a work plan to address all tasks in this work assignment. The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If a subcontractor(s) is proposed and subcontractors are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

This task also includes monthly progress and financial reports. The monthly progress report shall indicate in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs delineated by the tasks in this WA. These reports should also indicate an estimate for the next month by task and if any lagging costs are expected. EPA realizes these estimates are just approximate values and is interested in having this information for internal budgeting purposes.

Task 1.2: Information Quality Guidelines

The Contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines and shall complete the Checklist for Influential Information as needed for each deliverable from this work assignment as

they may be used in Agency decision-making and/or will be publicly available documents. The EPA WAM will provide the checklist to the Contractor. The Contractor shall provide a memorandum describing how the planned product(s) developed meet EPA's Information Quality Guidelines checklist. As part of that memo, the Contractor shall document the quality assurance procedures it used in developing the deliverables under this Work Assignment. The Contractor shall provide the memo at the time it delivers the Final Summary Report. The Contractor shall have a teleconference with the EPA WAM to discuss the Guidelines and the Contractor's role in completing the checklist..

Task 2: General Project Support and Development of TSM Considering Alternative Health Relationships

EPA is planning to make available guidance to States for consideration in developing site-specific Water Quality Standards (WQS) packages utilizing alternative human health associations with water quality measures. Task 2 comprises the different facets of the guidance development project and includes project planning, communication strategies, and document preparation.

Task 2.1. Project planning and management

The Contractor shall conduct project strategic planning in conjunction with the EPA WAM. The purpose of this subtask will be to develop a comprehensive plan that includes all related tasks and deliverables in the context of the Agency timeline for publishing RWQC and implementation guidance. The plan will also describe how each task or subtask will aid EPA in meeting its goals in regards to the publication of technical support materials in support of criteria implementation and may be iterative in nature. Project management coordination between the EPA WAM and the Contractor shall occur for the duration of the work assignment. Regular periodic meetings between the EPA WAM and the Contractor shall occur once the workplan has been approved.

Task 2.2. Project communication support

The contractor shall, based on technical direction given by the EPA WAM, provide support in preparing interim project updates and other materials for internal and external audiences. These may include, but are not limited to, short briefing documents and PowerPoint presentations. The Contractor may be requested to participate in briefings and meetings. The Contractor may also be requested to prepare reports for communication outside the EPA based on deliverables generated by tasks under this work assignment. The Contractor shall coordinate with the EPA WAM for the proper timing and need for these activities.

Interpretation and meta-analyses of epidemiological evidence are two potential technical areas that will need to be considered in the preparation of the TSM. The Contractor shall anticipate the need to discuss specific topics of a highly technical nature with ORD epidemiologists and also to convey the outcomes of such discussions to a non-technical audience.

Task 2.3: TSM document development

The purpose of this task is to develop a guide for use by States and localities for the purposes of deriving site-specific water quality criteria derived from alternative human health relationships to water quality, including information for evaluating the technical basis for the site-specific criteria. This guide should also provide information for EPA, particularly for Regional personnel who are tasked to evaluate State WQS packages. This document shall discuss a process to help States determine if a water body is eligible for the development of site-specific criteria, what information can be used to provide a line of evidence approach for demonstrating human health relationships with water quality, the differing approaches to establishing human health relationships with water quality, a comparison of site-specific health relationships to those used by EPA as a basis for the nationally recommended water quality criteria, a potential epidemiological and Quantitative Microbial Risk Assessment (QMRA) hybrid approach for demonstrating human health relationships, how to prepare a site-specific water quality standards package, and other topics as needed to be specified by the EPA WAM (and in consultation with HECD's partners in SHPD). The main goal for this deliverable is to produce guidance for use by States in developing microbial WQS that are scientifically defensible, protective of the recreational designated use, and meet EPA standards for consideration and potential approval.

This document should be clear to a potentially non-technical audience on the state of the science for epidemiology and risk assessment. For example, a good discussion will be needed for comparing results from various epidemiological studies conducted with different study designs. The discussion should include what the differences between the study designs are and what impact they have on the potential interpretation of the results, particularly in terms of comparing study results to EPA's recommendations. This type of discussion will be important for evaluating the scientific defensibility and protection of the designated use for any site-specific criteria derived from alternative study designs. The Contractor shall use examples from the peer reviewed literature, where possible, to highlight this discussion.

The draft deliverable for this task (see table below) will need to be peer reviewed by a 3rd party. The Contractor shall respond to the peer reviewer comments as directed by the EPA WAM via technical direction in preparation of the final deliverable. The final deliverable shall be Section 508 compliant as specified in the US Rehabilitation Act internet-based publications.

This task will require the Contractor to attend meetings with the EPA WAM and other staff at EPA Headquarters during the period of performance for the purposes of project updates, planning and communication.

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA PO as needed and provided to the Contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the PO.

Milestone/Deliverable Table

| Task | Task # | Milestones and Due Dates |
|--|--------|---|
| Task 1: Work plan, monthly progress reports and quality assurance | | |
| Workplan | 1.1 | Within 15 calendar days of receipt of work assignment |
| Information Quality Guidelines | 1.2 | Discuss with EAP WAM within 15 calendar days of receipt of work assignment. IQG checklists due with final deliverable (can be included with QA materials). |
| Task 2: General Project Support | | |
| Project Planning and Management | 2.1 | Update current plan as needed. Schedule periodic meetings with EPA WAM after approval of workplan. |
| Project Communications Support | 2.2 | After the workplan approval, throughout the period of performance. Communication materials will be informed by the results and be targeted for different audiences. |

Technical Support Materials

2.3

Draft for internal review, 2/15/13 (communication materials included); EPA may have additional comments; quick turnaround on any comments so that the peer review can begin by mid-March, 3rd party peer review will take approximately 90 days; Contractor shall coordinate with EPA WAM on the response to comments; Final by 6/30/13 contingent on EPA comments.

Task Knowledge and Skills Required: The Contractor shall have expertise in preparing the materials associated with this work assignment and be knowledgeable with the various fields of discipline discussed, including epidemiology, microbial risk assessment, biostatistics, and environmental microbiology. The Contractor shall be familiar with the different programs under the CWA, use of water quality monitoring, determination of human exposure to environmental contaminant sources, and gastrointestinal (or other) disease endpoints, applications of epidemiological data, and other factors associated with needs in recreational water quality and CWA 304(a) criteria development. The Contractor shall also be able to communicate the study outcomes and recreational outbreak data to a non-technical audience.

General Requirements of the Work Assignment and Schedule:

Due Dates: The Contractor shall provide due dates that are mutually acceptable with the EPA WAM. The Contractor shall notify the EPA WAM in advance, if a due date will not be met and request a revised date.

Delays: The Contractor shall make every effort to ensure there are no Contractor-caused delays. If a delay is inevitable, it is the Contractor's responsibility to notify the EPA WAM at the first sign of said delay. A revised schedule will then be worked out.

Draft Documents: The Contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. EPA WAM will provide comments on draft submissions prior to submission of final documents.

Final Documents: The Contractor shall submit final documents both electronically and in hardcopy to EPA WAM.